

**EPA REGISTRATION NUMBER 59639-183 – VOL. 1**

Material Sent for Data Extraction

Reg. # 59639-183

Description: Agency ltr 7/6/12, label stamped notification 7/6/12, receipt for section 3, reg ltr 6/18/12, 8570-1 6/18/12, certification statement 6/18/12

☒ Material(s) Sent to Data Extraction Contractors:

☐ New Stamped Label Dated \_\_\_\_\_

☒ Notification Dated 7/6/12

☐ New CSF(s) Dated \_\_\_\_\_

☒ Other: AGENCY LTR 7/6/12

☐ Decision #: \_\_\_\_\_

☐ Other Action/Comments: \_\_\_\_\_

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Marianne Lewis

Phone: 308-8043 Division: IRB/RD

Date: 7/9/12



Receipt for Section 3

S: 918810 Resubmission: ☐ Yes ☒ No

Regulatory Type: Product Registration - Section 3 Fee For Service: ☐ Yes ☒ No

Application Type: Notification

Company: 59639 VALENT U.S.A. CORPORATION V

Risk Manager: Registration Division, Risk Management Team 1

Product #: 59639-183 Product Name: NIPSIT SUITE CEREALS OF SEED PROTECTAN

Override#:

Me Too Section3: Me Too Product Name:

Application Date: 08-Jun-2012 ijd OPP Rec'd Date: 19-Jun-2012 ijd

Front End Date: 19-Jun-2012 ijd Risk Manager Send Date: 20-Jun-2012 ijd

FFS Due Date: Negotiated Due Date:

OPP Target Date:

Fast Track: ☐ New Ingredient: ☐

Receipt Description: Label Notification

Form A: ☐ Signature Date: Form B: ☐ Signature Date:

New Ingredient Request Date:

New Ingredient Received Date:

Print Letter

Enter More Information

Tracking

Receipt Content Des

Paper Label

View/Edit

Mariame



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460



OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

JUL 6 2012

Sally S. Christopher  
Regulatory Analyst  
Valent U.S.A. Corporation  
1600 Riviera Ave., Suite 200  
Walnut Creek, CA 94596-8025

Subject: NipsIt Suite Cereals Of Seed Protectant  
Correction of redundant statement, product name, and a typo  
EPA Reg. No. 59639-183  
Notification Application Dated June 18, 2012

Dear Ms. Christopher:

The Agency has received your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10, dated June 18, 2012 for the product NipsIt Suite Cereals Of Seed Protectant, EPA Reg. No. 59639-183. The Registration Division (RD) has reviewed this request and finds that the actions requested fall within the scopes of PR Notice 98-10. The label submitted with the application has been stamped "Notification" and will be placed in our records.

If you have any questions, please call me directly at (703) 308-8043.

Sincerely,

A handwritten signature in black ink, appearing to read "Marianne Lewis", written over a horizontal line.

Marianne Lewis  
Insecticide-Rodenticide Branch  
Registration Division (7505P)  
Office of Pesticide Programs





**NOTIFICATION**

JUL 06 2012

**REDLINE COPY - NOTIFICATION**

**NipsIt™ SUITE Cereals OF Seed Protectant**

**A SEED TREATMENT PRODUCT PROVIDING SYSTEMIC SEED AND SEEDLING PROTECTION AGAINST LISTED EARLY SEASON CEREAL DISEASES AND WIREWORM**

Active Ingredients	By Wt.
Clothianidin <sup>1</sup> .....	2.93%
Metalaxyl <sup>2</sup> .....	0.88%
Metconazole <sup>3</sup> .....	0.44%
Other Ingredients.....	<u>95.75%</u>
Total .....	100%

<sup>1</sup>(E)-1-(2-chloro-1,3-thiazol-5-ylmethyl)-3-methyl-2-nitroguanidine

<sup>2</sup>N-(2,6-dimethylphenyl)-N-(methoxyacetyl)alanine methyl ester

<sup>3</sup>5-[(4-chlorophenyl)methyl]-2,2-dimethyl-1-(1H-1,2,4-triazol-1-ylmethyl)cyclopentanol

One gallon of *NipsIt SUITE* Cereals OF Seed Protectant contains 0.256 lbs clothianidin, 0.077 lbs metalaxyl, and 0.038 lbs metconazole.

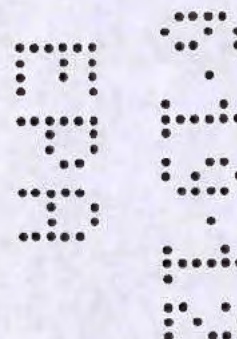
**KEEP OUT OF REACH OF CHILDREN**

**CAUTION**

**SEE NEXT PAGE FOR PRECAUTIONARY STATEMENTS**

**NET CONTENTS**

EPA Reg. No. 59639-183  
EPA Est. No.





# PRECAUTIONARY STATEMENTS

## HAZARDS TO HUMANS & DOMESTIC ANIMALS

### CAUTION

**PERSONAL PROTECTIVE EQUIPMENT (PPE):** Mixers, loaders, applicators and other handlers must wear: Long-sleeved shirt and long pants, chemical resistant gloves made of any waterproof material, socks and shoes.

Follow the manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry.

#### USER SAFETY RECOMMENDATIONS

Users should:

- Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.
- Remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

#### ENVIRONMENTAL HAZARDS

This product is toxic to aquatic invertebrates. Do not apply directly to water or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment wash water or rinsate. Do not apply where runoff is likely to occur. Drift and runoff may be hazardous to aquatic organisms in water adjacent to treated areas. Apply this product only as specified on label.

Treated seed exposed on soil surface maybe hazardous to birds. Cover or collect spilled seeds.

Metalaxyl has properties and characteristics associated with chemicals detected in ground water. This chemical may leach into ground water if used in areas where soils are permeable, particularly where the water table is shallow. Therefore, contain any product spills or equipment leaks and dispose of waste according to the disposal instructions on this label.

#### DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

**READ ENTIRE LABEL. USE STRICTLY IN ACCORDANCE WITH PRECAUTIONARY STATEMENTS AND DIRECTIONS AND WITH APPLICABLE STATE AND FEDERAL REGULATIONS.**

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the State or Tribal agency responsible for pesticide regulation.

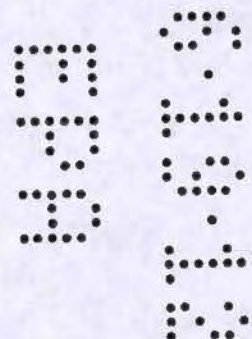


## AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR Part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted-entry interval. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the **restricted entry interval (REI) of 24 hours**.

**Exception:** Once the seeds are planted in soil, the Worker Protection Standard, under certain circumstances, allows workers to enter the treated area without restriction if there will be no worker contact with the soil subsurface or treated seed. PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is: long-sleeved shirt and long pants; chemical-resistant gloves such as barrier laminate, butyl rubber, nitrile rubber, or Viton; shoes plus socks.





**DISCLAIMER, RISKS OF USING THIS PRODUCT,  
LIMITED WARRANTY  
AND LIMITATION OF LIABILITY**

**IMPORTANT:** Read the entire Label including this Disclaimer, Risks of Using this Product, Limited Warranty, and Limitation of Liability before using this product. If the terms are not acceptable **THEN DO NOT USE THE PRODUCT**; rather, return the unopened product within 15 days of purchase for a refund of the purchase price.

**ASSUMPTION OF RISK**

The Buyer and User (referred to collectively herein as "Buyer") of this product should be aware that there are inherent unintended risks associated with the use of this product which are impossible to eliminate. These risks include, but are not limited to, injury to plants and crops to which this product is applied, lack of control of the target pests to this product. Such risks of crop injury, non-performance, or other unintended consequences are unavoidable and may result because of such factors as weather, soil conditions, disease, moisture conditions, irrigation practices, cultural practices or the manner of use or application, (or a combination of such factors) all of which are factors beyond the control of Valent. The Buyer should be aware that these inherent unintended risks may reduce the harvested yield of the crop in all or a portion of the treated acreage, or otherwise affect the crop such that additional care, treatment and expense are required to take the crop to harvest. If the Buyer chooses not to accept these risks, **THEN THIS PRODUCT SHOULD NOT BE APPLIED**. By applying this product Buyer acknowledges and accepts these inherent unintended risks **AND TO THE FULLEST EXTENT ALLOWED BY LAW, AGREES THAT ALL SUCH RISKS ASSOCIATED WITH THE APPLICATION AND USE ARE ASSUMED BY THE BUYER**.

Valent shall not be responsible for losses or damages (including, but not limited to, loss of yield, increased expenses of farming the crop or such incidental, consequential or special damages that may be claimed) resulting from use of this product in any manner not set forth on the label. Buyer assumes all risks associated with the use of this product in any manner or under conditions not specifically directed or approved on the label.

**LIMITED WARRANTY**

Valent warrants only that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated in the label, under average use conditions, when used strictly in accordance with the label **and subject to the Risks of Using This Product as described above. To the extent consistent with applicable law AND AS SET FORTH ABOVE, VALENT MAKES NO OTHER WARRANTIES, EITHER EXPRESSED OR IMPLIED**. No agent or representative of Valent or Seller is authorized to make or create any other express or implied warranty.

**LIMITATION OF LIABILITY**

To the fullest extent allowed by law, Valent or Seller is not liable for any incidental, consequential, indirect or special damages resulting from the use or handling of this product. The limitation includes, but is not limited to, loss of yield on all or any portion of the treated acreage, increased care, treatment or other expenses required to take the crop to harvest, increased finance charges or altered finance ratings, emotional or mental distress and/or exemplary damages. **TO THE FULLEST EXTENT ALLOWED BY LAW, THE EXCLUSIVE REMEDY OF THE BUYER, AND THE EXCLUSIVE MAXIMUM LIABILITY OF VALENT OR SELLER FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OF WARRANTY, CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE) RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT SHALL BE THE RETURN OF THE PURCHASE PRICE OF THIS PRODUCT OR, AT THE ELECTION OF VALENT OR SELLER, THE REPLACEMENT OF THE PRODUCT.**

**PROMPT NOTICE OF CLAIM**

To the extent consistent with applicable law allowing such requirements Valent must be provided notice as soon as Buyer has reason to believe it may have a claim, but in no event later than twenty-one days from date of planting, or twenty-one days from the date of application, whichever is latter, so that an immediate inspection of the affected property and growing crops can be made.

To the extent consistent with applicable law if Buyer does not notify Valent of any claims, in such period, it shall be barred from obtaining any remedy.

**NO AMENDMENTS**

Valent and Seller offer this product, and Buyer accepts it, subject to the foregoing **Disclaimer, Risks of Using This Product, Limited Warranty and Limitation of Liability**, which may not be modified by any oral or written agreement.



## RESISTANCE MANAGEMENT

*NipsIt SUITE* Cereals OF Seed Protectant contains Clothianidin which is a neonicotinoid and a Group 4A insecticide. Insect biotypes with acquired resistance to Group 4A insecticides may eventually dominate the insect population if Group 4A insecticides are used repeatedly in the same field or in successive years as the primary method of control for targeted species. This may result in partial or total loss of control of those species by *NipsIt SUITE* Cereals OF Seed Protectant or other Group 4A insecticides. Valent U.S.A. Corporation strives to maintain strong stewardship of this product by recommending that its use be coordinated in a planned resistance management strategy program established for the specific crop and area.

Contact your local extension specialist, certified crop advisors and/or manufacturer for insecticide resistance management or IPM recommendations for the specific site and resistant pest problems.

For further information or to report suspected resistance, you may contact Valent U.S.A. Corporation at 800-682-5368.

## PRECAUTIONS AND RESTRICTIONS

*NipsIt SUITE* Cereals OF Seed Protectant is formulated as a ready-to-use seed protectant formulation and must be used only in accordance with specifications on this label utilizing mechanical, slurry, or mist-type seed treating equipment, provided that the equipment can be calibrated to accurately and uniformly apply the product to seed. This product is for both commercial and on-farm application. Do not use planter box or hopper box when applying product to seeds. Always mix product thoroughly before use.

As stated by regulations specified in 40 CFR 153.155, all seed treated with *NipsIt SUITE* Cereals OF Seed Protectant must be colored with an EPA-approved dye or colorant to visually distinguish seed that is treated with a pesticide. This product contains such dye or colorant. This regulation is necessary to prevent treated seed from accidental use as a food for man or feed for animals.

## Seed Quality and Storage of Treated Seed

Seed treatments applied to low vigor or poor quality seed or to mechanically damaged seed may result in loss of seed germination or reduced seedling vigor. To verify seed safety, treat a small portion of seed prior to treatment of an entire seed lot. Utilize standard seed germination methodologies to determine and verify seed safety. Proper storage conditions of treated seed are recommended. Due to seed quality and seed storage conditions beyond the control of Valent U.S.A. Corporation, no claims are made to guarantee the germination of carry-over treated seed.

## SEED BAG TAG

The Federal Seed Act requires that the container of seed treated with *NipsIt SUITE* Cereals OF Seed Protectant containing clothianidin, metalaxyl, and metconazole must be labeled with the following statements:

- This seed has been treated with *NipsIt SUITE* Cereals OF Seed Protectant which contains clothianidin, metalaxyl and metconazole.
- Do not use treated seed for feed, food or oil processing.



In addition, the U.S. Environmental Protection Agency requires the following statements on the container of seed treated with *NipsIt SUITE* Cereals OF Seed Protectant:

- Regardless of the type of application (seed treatment, soil or foliar), do not apply more than a total of 6.4 oz (181.4 gram) clothianidin (active ingredient) per acre per cropping cycle.
- Store away from feeds and other foodstuffs.
- Excess treated seed may be used for ethanol production only if (1) by-products are not used for livestock feed and (2) no measurable residues of pesticide remain in ethanol by-products that are used in agronomic practice.
- Wear long sleeved shirt, long pants and chemical resistant gloves when handling treated seed.
- Dispose of all excess treated seed. Left over treated seed may be double-sown around the headland or buried away from water sources in accordance with local requirements. Do not contaminate water bodies when disposing of planting equipment washwaters.
- Treated seeds must be planted at a minimum depth of 0.5 inch.
- This compound is toxic to birds and mammals. Treated clothianidin seeds exposed on soil surface may be hazardous to birds and mammals. Cover or collect seeds spilled during loading.
- This compound is highly toxic to bees exposed directly (contact). Ensure that planting equipment is functioning properly in accordance with manufacturing recommendations to minimize seed coat abrasion during planting to reduce dust which can drift to blooming crops or weeds.
- Do not re-use bags from treated seed to handle food or feed products.
- Dispose of seed packaging in accordance with local requirements.
- ~~The compound is toxic to birds and mammals. Treated clothianidin seeds exposed on soil surface may be hazardous to birds and mammals. Cover or collect seeds spilled during loading.~~
- -After seeds have been planted, do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 24 hours. Exception: Once seeds are planted and covered by soil or other planting media, the Worker Protection Standard (WPS) allows workers to enter the treated area without restriction."
- Areas planted with treated seed of barley, oats and wheat may be replanted immediately with bulb vegetables, canola, cereal grains (except rice), cotton, fruiting vegetables (including cucurbits), leafy vegetables (including brassica vegetables), rapeseed, root and tuber vegetables and soybean. These areas may also be replanted after 30 days with dry beans, grasses, non-grass animal feeds and rice. These areas may also be replanted after 8 months with sugarcane. Do not plant any other crop in the treated area for at least one year after these treated seeds are planted.

## PRODUCT INFORMATION

*NipsIt SUITE* Cereals OF Seed Protectant is a systemic fungicide plus insecticide product formulated for seed treatment use to provide protection against seed-borne and soil-borne diseases and seed protection against wireworm. The fungicide active ingredients in *NipsIt SUITE* Cereals OF Seed Protectant are metconazole, a broad-spectrum, systemic, triazole fungicide, and metalaxyl, an Oomycete-active, systemic acylalanine fungicide. The fungicide components of *NipsIt SUITE* Cereals OF Seed Protectant provide activity against *Pythium spp.*, *Rhizoctonia solani*, *Fusarium spp.*, and other Deuteromycete and Basidiomycete (smut and bunt) fungi. Clothianidin is a systemic insecticide in *NipsIt SUITE* Cereals OF Seed Protectant giving seed protection against wireworm.



## MODES OF ACTION

Metalaxyl fungicide contained in *NipsIt* **INSIDE SUITE** Cereals OF Seed Protectant is a member of the acylalanine chemical group (FRAC Code 4) and interrupts fungal nucleic acid synthesis. Metconazole belongs to the sterol biosynthesis inhibitor group of fungicides (FRAC Code 3). Clothianidin is a neonicotinoid insecticide (IRAC MoA Group 4A) acting as a nicotine acetylcholine receptor agonist/antagonist in insect metabolism.

## APPLICATION DIRECTIONS

Accurate application of *NipsIt* **SUITE** Cereals OF Seed Protectant to seed is required for control of pests. *NipsIt* **SUITE** Cereals OF Seed Protectant is ready to use and may be applied direct to seed as formulated. However, to enhance uniform seed coverage, dilution with water may be appropriate for some types of treaters and/or treating seed under dry and/or hot conditions. If so, mix *NipsIt* **SUITE** Cereals OF Seed Protectant and water thoroughly into slurry before treating seed. Recalibrate treating equipment to compensate for the addition of water. The amount of dilution water that is most suitable depends on the seed, treating equipment, and the temperature.

For preparation of product in a slurry mixture with water, use the following guideline:

<i>NipsIt</i> <b>SUITE</b> Cereals OF Seed Protectant Use Rate:	Amount of water to be added to product:	Total Slurry Volume to apply per cwt. seed:
5.0 fl.oz./cwt. seed	5.0 – 10 fl.oz.	10.0 – 15 fl.oz.
7.5 fl.oz./cwt. seed	7.5 fl.oz./cwt.	15 fl.oz./cwt.

Use standard slurry or mist-type seed treatment equipment.

The following tables provide use rates of *NipsIt* **SUITE** Cereals OF Seed Protectant by labeled crop, with disease and insect protection guidelines:

BARLEY			
Seed/Seedling Diseases	Insect Pests	<i>NipsIt</i> <b>SUITE</b> Cereals OF Seed Protectant Use Rates	
		fl oz/100 lbs seed	<sup>1</sup> active Ingredient (mg ai/seed)
Covered Smut Loose Smut Seed Decay Fungi Fusarium Seed Scab Pythium Seed Rot and Seedling Dieback Early Season Fusarium Seedling Dieback Early Season Rhizoctonia Root Rot Early Season Common Root Rot	Wireworm	5.0 -7.5	Clothianidin (0.00333 -0.005)  Metalaxyl (0.001 -0.0015)  Metconazole (0.00049-0.00074)
Regardless of type of application (seed treatment, soil or foliar ), do not apply more than a total of 6.4 oz (181.4 gram) active ingredient clothianidin per acre per cropping cycle.			

<sup>1</sup>mg active ingredient per seed is based on 13,605 seeds per pound



OATS			
Seed/Seedling Diseases	Insect Pests	NipsIt SUITE Cereals OF Seed Protectant Use Rates	
		fl oz/100 lbs seed	<sup>1</sup> active Ingredient (mg ai/seed )
Loose Smut Seed Decay Fungi Fusarium Seed Scab Pythium Seed Rot and Seedling Dieback Early Season Fusarium Seedling Dieback Early Season Rhizoctonia Root Rot Early Season Common Root Rot	Wireworm	5.0 -7.5	Clothianidin (0.00238 -0.00357)  Metalaxyl (0.00072 -0.00107)  Metconazole (0.00035-0.00053)
Regardless of type of application (seed treatment, soil or foliar ), do not apply more than a total of 6.4 oz (181.4 gram) active ingredient clothianidin per acre per cropping cycle			

<sup>1</sup> mg active ingredient per seed is based on 19,047 seeds per pound



WHEAT			
Seed/Seedling Diseases	Insect Pests	NipsIt SUITE Cereals OF Seed Protectant Use Rates	
		fl oz/100 lbs seed	<sup>1</sup> active Ingredient (mg.ai/seed)
Common Bunt Flag Smut Loose Smut Seed Decay Fungi Fusarium Seed Scab Pythium Seed Rot and Seedling Dieback Early Season Fusarium Seedling Dieback Early Season Rhizoctonia Root Rot Early Season Common Root Rot	Wireworm	5.0 -7.5	Clothianidin (0.004 -0.006mg)  Metalaxyl (0.0012 -0.0018 mg)  Metconazole (0.00059-0.00089 mg)
Regardless of type of application (seed treatment, soil or foliar ), do not apply more than a total of 6.4 oz (181.4 gram) active ingredient clothianidin per acre per cropping cycle			

<sup>1</sup> mg active ingredient per seed is based on 11,338 seeds per pound



## STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage and disposal.

### PESTICIDE STORAGE

Store in a dry place away from excessive heat.

Do not store near food or feed.

Store in original container only.

To close package, replace and tighten cap to form an airtight seal.

### PESTICIDE DISPOSAL

To avoid wastes, use all material in this container by application according to label directions. If wastes cannot be avoided, offer remaining product to a waste facility or pesticide disposal program (often such programs are run by state or local governments or by industry).

### CONTAINER HANDLING

*[Use the following statement for containers equal to or less than 5 gallons]*

Nonrefillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container 1/4 full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Offer for recycling, if available; otherwise dispose of in a sanitary landfill or incinerator.

*[Use the following statement for containers greater than 5 gallons]*

Nonrefillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container 1/4 full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times. Offer for recycling, if available; otherwise dispose of in a sanitary landfill or incinerator.

*[Use the following statement for all formulation types/all refillable container types]*

Refillable container. Refill this container with pesticide only. Do not reuse this container for any other purpose. Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. To clean the container before final disposal, empty the remaining contents from this container into application equipment or mix tank. Fill the container about 10 percent full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this rinsing procedure two more times. Offer for recycling, if available; otherwise dispose of in a sanitary landfill or incineration.

### RECYCLING

Once cleaned, some agricultural plastic pesticide containers can be taken to a container collection site or picked up for recycling. To find the nearest site, contact your chemical dealer or manufacturer, or contact the Ag Container Recycling Council (ACRC) at 877-952-2272 (toll free) or [www.acrecycle.org](http://www.acrecycle.org).



*NipsIt* is a trademark of Valent U.S.A. Corporation

Copyright© 2012 by Valent U.S.A. Corporation

Manufactured For:

**Valent U.S.A. Corporation**

P. O. Box 8025

Walnut Creek CA 94596-8025

Made in U.S.A.

EPA Reg. No. 59639-183

EPA Est. No.

059639-00183.20120618.NIP.NOTIF

20120417/20111220.NIP.Cereal,rev1.FINAL





June 18, 2012

**NipsIt™ SUITE Cereals OF Seed Protectant,  
EPA Reg. No. 59639-183  
Active Ingredients:  
Clothianidin, Metalaxyl, Metconazole  
NOTIFICATION**

Ms. Mariann Lewis  
U.S. Environmental Protection Agency (NOTIF)  
Insecticide-Rodenticide Branch  
Registration Division (7505P)  
1200 Pennsylvania Ave. NW  
Washington, DC 20460

Dear Ms. Lewis:

Valent U.S.A. Corporation would like to update our product label via Notification for NipsIt™ SUITE Cereals OF Seed Protectant (EPA Reg. No. 59639-183), which contains the active ingredients clothianidin, metalaxyl and metconazole. The update includes the following:

The removal of one redundant bullet point on page 6, correction of the product name on page 7 and the addition of a parenthesis on page 10.

Please find enclosed the following documents to support this notification:

- Pesticide application (Form 8570-1)
- A Certification Statement consistent with the provisions of PR-Notice 98-10
- One (1) copy of the proposed label
- One (1) copy of the proposed label with redline additions/strike through
- A CD with proposed label in PDF format
- The statement of Certification with Respect to Label Integrity

If you should have any questions please contact me at (925) 256-2710 or email [sally.christopher@valent.com](mailto:sally.christopher@valent.com) or Sue-Chi Shen at (972) 244-6543 or email [sue.shen@valent.com](mailto:sue.shen@valent.com).

Sincerely,

A handwritten signature in black ink that reads "Sally S. Christopher". The signature is written in a cursive, flowing style.

Sally S. Christopher  
Regulatory Analyst  
Registration and Regulatory Affairs

Enclosures





United States  
Environmental Protection Agency  
Washington, DC 20460

☐ Registration  
☐ Amendment  
☒ Other

OPP Identifier Number

**Application for Pesticide - Section I**

1. Company/Product Number 59639-183	2. EPA Product Manager Marianne Lewis	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) NipsIt SUITE Cereals OF Seed Protectant	PM# 01	
5. Name and Address of Applicant (Include ZIP Code) Valent U.S.A. Corporation 1600 Riviera Ave., Suite 200 Walnut Creek, CA 94596-8025 <input type="checkbox"/> Check if this is a new address	6. <b>Expedited Review.</b> In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

**Section - II**

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

**Explanation:** Use additional page(s) if necessary. (For section I and Section II.)

NOTIFICATION: Correction of redundant statement and product name and a typo.

**Section - III**

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal	
				<input checked="" type="checkbox"/> Plastic	
				<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) _____	
* Certification must be submitted					
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input checked="" type="checkbox"/> On Labeling	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

**Section - IV**

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Sally S. Christopher		Title Regulatory Analyst	
		Telephone No. (Include Area Code) 925-256-2710	
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped)
2. Signature 		3. Title Regulatory Analyst	
4. Typed Name Sally S. Christopher		5. Date June 18, 2012	





# Certification with Respect to Label Integrity

version: 9/11/02

I certify that the information (including, but not limited to, text, tables, and graphics) contained in the electronic file identified below by file name and submitted with this certification is the same information as that on the paper copies of these documents included with this submission.

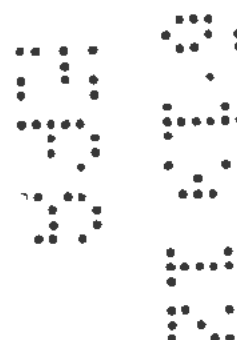
PROPOSED LABEL		
EPA Registration #	Date Submitted to EPA	Electronic file name
59639-183	06/18/2012	0059639-00183.20120618.NIP.Cereal.NOTIF.pdf

I certify that the statements that I have made on this form are true, accurate, and complete. I acknowledge that any knowingly false or misleading statements may be punishable by fine or imprisonment or both under applicable law.

Sally S. Christopher  
Signature

June 18, 2012  
Date

Sally S. Christopher  
Regulatory Analyst  
Registration and Regulatory Affairs  
Valent U.S.A. Corporation







June 18, 2012

**NipsIt™ SUITE Cereals OF Seed Protectant,  
EPA Reg. No. 59639-183  
Active Ingredients:  
Clothianidin, Metalaxyl, Metconazole  
NOTIFICATION**

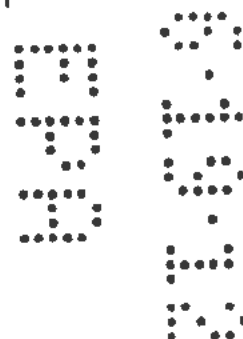
### **CERTIFICATION STATEMENT**

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Sincerely,

A handwritten signature in cursive script that reads "Sally S. Christopher".

Sally S. Christopher  
Regulatory Analyst  
Registration and Regulatory Affairs  
Valent U.S.A. Corporation





# Material Sent for Data Extraction

Reg. # S9639-183

Description: CSF Amend

☒ Material(s) Sent to Data Extraction Contractors:

☐ New Stamped Label Dated \_\_\_\_\_

☐ Notification Dated \_\_\_\_\_

☒ New CSF(s) Dated 2/26/12, 2/27/12, 2/28/12

☐ Other: \_\_\_\_\_

☐ Decision #: \_\_\_\_\_

☐ Other Action/Comments: \_\_\_\_\_

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Jennifer Urbanski

Phone: 347-0156 Division: RD

Date: 5/9/12





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

Sue-Chi Shen  
Valent USA Corporation  
1600 Riviera Ave, Suite 200  
Walnut Creek, CA 94596

MAY 09 2012

Dear Ms. Shen:

Subject: Revised Basic, Alternate 1 and Alternate 2 CSFs; EPA Reg. # added  
NipsIt SUITE Cereals OF Seed Protectant  
EPA Registration No. 59639-183  
Submission Date: February 28, 2012

The Agency has reviewed your submission for three revised Confidential Statements of Formula, and the following comment apply:

The Confidential Statement of Formula dated February 26, 2012 for the basic formulation agrees with the label claim in compliance with PR Notice 91-2 and is acceptable. The revised CSF will replace the previously accepted basic CSF.

The Confidential Statement of Formula dated February 27, 2012 for the alternate formulation (alternate #1) agrees with the label claim in compliance with PR Notice 91-2 and is acceptable. The revised CSF will replace the previously accepted Alternate #1 CSF.

The Confidential Statement of Formula dated February 28, 2012 for the alternate formulation (alternate #2) agrees with the label claim in compliance with PR Notice 91-2 and is acceptable. The revised CSF will replace the previously accepted Alternate #2 CSF.

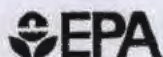
The Confidential Statements of Formula have been added to your file as part of the record. If you have any questions concerning this letter, please contact Dr. Jennifer Urbanski at (703) 347-0156 or [urbanski.jennifer@epa.gov](mailto:urbanski.jennifer@epa.gov).

Sincerely yours,

A handwritten signature in cursive script that reads "Venus Eagle".

Venus Eagle  
Product Manager (01)  
Insecticide-Rodenticide Branch  
Registration Division (7505P)





United States  
Environmental Protection Agency  
Washington, DC 20460

☐ Registration  
☐ Amendment  
☒ Other

OPP Identifier Number

## Application for Pesticide - Section I

1. Company/Product Number 59639-183	2. EPA Product Manager Venus Eagle	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Nipsit SUITE Cereals OF Seed Protectant	PM# 1	
5. Name and Address of Applicant (Include ZIP Code) Valent U.S.A. Corporation, 1600 Riviera Ave, Suite 200, Walnut Creek, CA 94596-8025  <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to:  <input checked="" type="checkbox"/> EPA Reg. No. _____ Product Name _____	

## Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input checked="" type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

To provide revised and updated Confidential Statement of Formula's for Nipsit Suite Cereals OF Seed Protectant.

## Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal	
* Certification must be submitted				<input type="checkbox"/> Plastic	
If "Yes" Unit Packaging wgt. No. per container		If "Yes" Package wgt. No. per container		<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input checked="" type="checkbox"/> Other (Specify) _____	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 2.5 gal and 260		5. Location of Label Directions <input type="checkbox"/> On Label <input checked="" type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

## Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Sue-Chi Shen	Title Project Manager	Telephone No. (Include Area Code) 214-784-5536
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)  
2. Signature 	3. Title Project Manager	
4. Typed Name Sue-Chi Shen	5. Date 2/28/2012	





FW: Request a new set of CSFs for 59639-183, 59639-184 and 59639-187 with new dates  
Shen, Sue

to:

Jennifer Urbanski

05/03/2012 01:58 PM

Hide Details

From: "Shen, Sue" <Sue.Shen@valent.com>

To: Jennifer Urbanski/DC/USEPA/US@EPA

4 Attachments



ValentStationary3.jpg SKMBT\_C36012050308482.pdf SKMBT\_C36012050308481.pdf



SKMBT\_C36012050308480.pdf

Jennifer : Per your request, please see the CSFs with the new dates for products 59639-183, 59639-184 and 59639-187.

Sorry for the delay of fulfilling your request.



---

**Sue-Chi Shen**

Regulatory Project Manager

Valent U.S.A. Corporation

2301 Ohio Drive, Suite 137 Plano, TX 75093

Direct (972) 244-6543 Mobile (214) 784-5536 Confidential Fax (925) 817-5910



---

From: Jennifer Urbanski/DC/USEPA/US  
To: sally.christopher@valent.com  
Date: 03/14/2012 10:58 AM  
Subject: 59639-183, 59639-184 and 59639-187

---

Hi Sally, can you please send me the revised CSFs for the above products after changing the date of the CSFs to match the date of your 8570-1 form? Thanks a bunch, it keeps everything clear in our records.

Best,  
Jenn

Jennifer Urbanski, Ph.D., Biologist  
Insecticide-Rodenticide Branch, S7221  
Registration Division (7505P)  
U.S. Environmental Protection Agency  
1200 Pennsylvania Ave. NW  
Washington, DC 20460  
(703) 347-0156





FW: Valent U.S.A.: 8570-1 Forms for NipsIt Cereal and Canola  
Christopher, Sally

to:

Venus Eagle

02/28/2012 07:10 PM

Hide Details

From: "Christopher, Sally" <Sally.Christopher@valent.com>

To: Venus Eagle/DC/USEPA/US@EPA

3 Attachments



ValentStationary3.jpg cereal-183.pdf canola-184.pdf

---

**From:** Christopher, Sally

**Sent:** Tuesday, February 28, 2012 4:07 PM

**To:** 'venus.eagle@epa.gov'

**Cc:** Shen, Sue; Pereira, Regiane; White, Larry

**Subject:** Valent U.S.A.: 8570-1 Forms for NipsIt Cereal and Canola

Hello Venus,

Per our phone conversation on Feb 28, please find attached the two 8570-1 forms you requested for the CSF's that accompanied our FPL submissions on February 16, 2012. The products are:

NipsIt SUITE Cereals OF Seed Protectant, EPA Reg. No. 59639-183

NipsIt SUITE Canola Seed Protectant, EPA Reg. No. 59639-184

Thank you for letting me know that the two items (FPL vs CSF) are considered two different action items by the Agency.

Please let me know if you need any additional information.



Thank You,

Sally



---

**Sally S. Christopher**

Regulatory Analyst

Valent U.S.A. Corporation

1600 Riviera Ave, Suite 200 Walnut Creek, CA 94596-8025

**Direct** (925) 256-2710 **Fax** (925) 948-3488





Valent U.S.A. Corporation  
Registration & Regulatory Affairs  
1101 14<sup>th</sup> St., NW, Suite 1050  
Washington, DC 20005  
(202) 872-4688

February 16, 2012

Nipsit<sup>®</sup> SUITE Cereals Seed Protectant  
EPA Reg. No. 59639-183  
**FINAL PRINTED LABEL**

Ms. Venus Eagle  
U.S. Environmental Protection Agency  
Insecticide-Rodenticide Branch  
Registration Division (7505P)  
1200 Pennsylvania Ave. NW  
Washington, DC 20460

Dear Ms. Eagle:

Please find enclosed two copies of the following Section 3 label that is marked  
'Final Printed Label':

- **Nipsit<sup>®</sup> SUITE Cereals Seed Protectant, EPA Reg. No. 59639-183**

Also enclosed are copies of the Confidential Statements of Formula (EPA Form 8570-4)  
for the basic formulation and two alternate formulas with the revised EPA Registration  
Number, 59639-183.

If you need any further information, you can contact me at [sally.christopher@valent.com](mailto:sally.christopher@valent.com)  
or by phone at (925) 256-2710.

Thank you for your timely response in approving this label.

Sincerely,

Sally S. Christopher  
Regulatory Analyst  
Registrations and Regulatory Affairs  
Valent U.S. A. Corporation

enclosure



## FINAL PRINTED LABEL



NOT REVIEWED  
In Accordance with PR Notice 82-2  
Based on Draft Labeling Dated  
DEC. 21, 2011

### NipsIt™ SUITE Cereals OF Seed Protectant

A SEED TREATMENT PRODUCT PROVIDING SYSTEMIC SEED AND SEEDLING PROTECTION AGAINST LISTED EARLY SEASON CEREAL DISEASES AND WIREWORM

Active Ingredients	By Wt.
Clothianidin <sup>1</sup> .....	2.93%
Metalaxyl <sup>2</sup> .....	0.88%
Metconazole <sup>3</sup> .....	0.44%
Other Ingredients .....	95.75%
Total .....	100%

<sup>1</sup>(E)-1-(2-chloro-1,3-thiazol-5-ylmethyl)-3-methyl-2-nitroguanidine

<sup>2</sup>N-(2,6-dimethylphenyl)-N-(methoxyacetyl)alanine methyl ester

<sup>3</sup>5-[(4-chlorophenyl)methyl]-2,2-dimethyl-1-(1H-1,2,4-triazol-1-ylmethyl)cyclopentanol

One gallon of *NipsIt SUITE* Cereals OF Seed Protectant contains 0.256 lbs clothianidin, 0.077 lbs metalaxyl, and 0.038 lbs metconazole.

**KEEP OUT OF REACH OF CHILDREN**

**SEE NEXT PAGE FOR PRECAUTIONARY STATEMENTS**

#### NET CONTENTS

EPA Reg. No. 59639-183

EPA Est. No.



## PRECAUTIONARY STATEMENTS

### HAZARDS TO HUMANS & DOMESTIC ANIMALS

#### PERSONAL PROTECTIVE EQUIPMENT (PPE):

**Mixers, loaders, applicators and other handlers must wear:** Long-sleeved shirt and long pants, chemical resistant gloves made of any waterproof material, socks and shoes.

Follow the manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry.

#### USER SAFETY RECOMMENDATIONS

Users should:

- Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.
- Remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

### ENVIRONMENTAL HAZARDS

This product is toxic to aquatic invertebrates. Do not apply directly to water or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment wash water or rinsate. Do not apply where runoff is likely to occur. Drift and runoff may be hazardous to aquatic organisms in water adjacent to treated areas. Apply this product only as specified on label.

Treated seed exposed on soil surface maybe hazardous to birds. Cover or collect spilled seeds.

Metalaxyl has properties and characteristics associated with chemicals detected in ground water. This chemical may leach into ground water if used in areas where soils are permeable, particularly where the water table is shallow. Therefore, contain any product spills or equipment leaks and dispose of waste according to the disposal instructions on this label.

### DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

**READ ENTIRE LABEL. USE STRICTLY IN ACCORDANCE WITH PRECAUTIONARY STATEMENTS AND DIRECTIONS AND WITH APPLICABLE STATE AND FEDERAL REGULATIONS.**

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the State or Tribal agency responsible for pesticide regulation.



## AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR Part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted-entry interval. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the **restricted entry interval (REI) of 24 hours.**

**Exception:** Once the seeds are planted in soil, the Worker Protection Standard, under certain circumstances, allows workers to enter the treated area without restriction if there will be no worker contact with the soil subsurface or treated seed. PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is: long-sleeved shirt and long pants; chemical-resistant gloves such as barrier laminate, butyl rubber, nitrile rubber, or Viton; shoes plus socks.



**DISCLAIMER, RISKS OF USING THIS PRODUCT,  
LIMITED WARRANTY  
AND LIMITATION OF LIABILITY**

**IMPORTANT:** Read the entire Label including this Disclaimer, Risks of Using this Product, Limited Warranty, and Limitation of Liability before using this product. If the terms are not acceptable THEN DO NOT USE THE PRODUCT; rather, return the unopened product within 15 days of purchase for a refund of the purchase price.

**ASSUMPTION OF RISK**

The Buyer and User (referred to collectively herein as "Buyer") of this product should be aware that there are inherent unintended risks associated with the use of this product which are impossible to eliminate. These risks include, but are not limited to, injury to plants and crops to which this product is applied, lack of control of the target pests to this product. Such risks of crop injury, non-performance, or other unintended consequences are unavoidable and may result because of such factors as weather, soil conditions, disease, moisture conditions, irrigation practices, cultural practices or the manner of use or application, (or a combination of such factors) all of which are factors beyond the control of Valent. The Buyer should be aware that these inherent unintended risks may reduce the harvested yield of the crop in all or a portion of the treated acreage, or otherwise affect the crop such that additional care, treatment and expense are required to take the crop to harvest. If the Buyer chooses not to accept these risks, THEN THIS PRODUCT SHOULD NOT BE APPLIED. By applying this product Buyer acknowledges and accepts these inherent unintended risks AND TO THE FULLEST EXTENT ALLOWED BY LAW, AGREES THAT ALL SUCH RISKS ASSOCIATED WITH THE APPLICATION AND USE ARE ASSUMED BY THE BUYER.

Valent shall not be responsible for losses or damages (including, but not limited to, loss of yield, increased expenses of farming the crop or such incidental, consequential or special damages that may be claimed) resulting from use of this product in any manner not set forth on the label. Buyer assumes all risks associated with the use of this product in any manner or under conditions not specifically directed or approved on the label.

**LIMITED WARRANTY**

Valent warrants only that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated in the label, under average use conditions, when used strictly in accordance with the label and subject to the Risks of Using This Product as described above. To the extent consistent with applicable law AND AS SET FORTH ABOVE, VALENT MAKES NO OTHER WARRANTIES, EITHER EXPRESSED OR IMPLIED. No agent or representative of Valent or Seller is authorized to make or create any other express or implied warranty.

**LIMITATION OF LIABILITY**

To the fullest extent allowed by law, Valent or Seller is not liable for any incidental, consequential, indirect or special damages resulting from the use or handling of this product. The limitation includes, but is not limited to, loss of yield on all or any portion of the treated acreage, increased care, treatment or other expenses required to take the crop to harvest, increased finance charges or altered finance ratings, emotional or mental distress and/or exemplary damages. TO THE FULLEST EXTENT ALLOWED BY LAW, THE EXCLUSIVE REMEDY OF THE BUYER, AND THE EXCLUSIVE MAXIMUM LIABILITY OF VALENT OR SELLER FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OF WARRANTY, CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE) RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT SHALL BE THE RETURN OF THE PURCHASE PRICE OF THIS PRODUCT OR, AT THE ELECTION OF VALENT OR SELLER, THE REPLACEMENT OF THE PRODUCT.

**PROMPT NOTICE OF CLAIM**

To the extent consistent with applicable law allowing such requirements Valent must be provided notice as soon as Buyer has reason to believe it may have a claim, but in no event later than twenty-one days from date of planting, or twenty-one days from the date of application, whichever is latter, so that an immediate inspection of the affected property and growing crops can be made.

To the extent consistent with applicable law if Buyer does not notify Valent of any claims, in such period, it shall be barred from obtaining any remedy.

**NO AMENDMENTS**

Valent and Seller offer this product, and Buyer accepts it, subject to the foregoing Disclaimer, Risks of Using This Product, Limited Warranty and Limitation of Liability, which may not be modified by any oral or written agreement.



## RESISTANCE MANAGEMENT

*NipsIt SUITE* Cereals OF Seed Protectant contains Clothianidin which is a neonicotinoid and a Group 4A insecticide. Insect biotypes with acquired resistance to Group 4A insecticides may eventually dominate the insect population if Group 4A insecticides are used repeatedly in the same field or in successive years as the primary method of control for targeted species. This may result in partial or total loss of control of those species by *NipsIt SUITE* Cereals OF Seed Protectant or other Group 4A insecticides. Valent U.S.A. Corporation strives to maintain strong stewardship of this product by recommending that its use be coordinated in a planned resistance management strategy program established for the specific crop and area.

Contact your local extension specialist, certified crop advisors and/or manufacturer for insecticide resistance management or IPM recommendations for the specific site and resistant pest problems.

For further information or to report suspected resistance, you may contact Valent U.S.A. Corporation at 800-682-5368.

## PRECAUTIONS AND RESTRICTIONS

*NipsIt SUITE* Cereals OF Seed Protectant is formulated as a ready-to-use seed protectant formulation and must be used only in accordance with specifications on this label utilizing mechanical, slurry, or mist-type seed treating equipment, provided that the equipment can be calibrated to accurately and uniformly apply the product to seed. This product is for both commercial and on-farm application. Do not use planter box or hopper box when applying product to seeds. Always mix product thoroughly before use.

As stated by regulations specified in 40 CFR 153.155, all seed treated with *NipsIt SUITE* Cereals OF Seed Protectant must be colored with an EPA-approved dye or colorant to visually distinguish seed that is treated with a pesticide. This product contains such dye or colorant. This regulation is necessary to prevent treated seed from accidental use as a food for man or feed for animals.

## Seed Quality and Storage of Treated Seed

Seed treatments applied to low vigor or poor quality seed or to mechanically damaged seed may result in loss of seed germination or reduced seedling vigor. To verify seed safety, treat a small portion of seed prior to treatment of an entire seed lot. Utilize standard seed germination methodologies to determine and verify seed safety. Proper storage conditions of treated seed are recommended. Due to seed quality and seed storage conditions beyond the control of Valent U.S.A. Corporation, no claims are made to guarantee the germination of carry-over treated seed.

## SEED BAG TAG

The Federal Seed Act requires that the container of seed treated with *NipsIt SUITE* Cereals OF Seed Protectant containing clothianidin, metalaxyl, and metconazole must be labeled with the following statements:

- This seed has been treated with *NipsIt SUITE* Cereals OF Seed Protectant which contains clothianidin, metalaxyl and metconazole.
- Do not use treated seed for feed, food or oil processing.



In addition, the U.S. Environmental Protection Agency requires the following statements on the container of seed treated with *NipsIt SUITE* Cereals OF Seed Protectant:

- Regardless of the type of application (seed treatment, soil or foliar), do not apply more than a total of 6.4 oz (181.4 gram) clothianidin (active ingredient) per acre per cropping cycle.
- Store away from feeds and other foodstuffs.
- Excess treated seed may be used for ethanol production only if (1) by-products are not used for livestock feed and (2) no measurable residues of pesticide remain in ethanol by-products that are used in agronomic practice.
- Wear long sleeved shirt, long pants and chemical resistant gloves when handling treated seed.
- Dispose of all excess treated seed. Left over treated seed may be double-sown around the headland or buried away from water sources in accordance with local requirements. Do not contaminate water bodies when disposing of planting equipment washwaters.
- Treated seeds must be planted at a minimum depth of 0.5 inch.
- This compound is toxic to birds and mammals. Treated clothianidin seeds exposed on soil surface may be hazardous to birds and mammals. Cover or collect seeds spilled during loading.
- This compound is highly toxic to bees exposed directly (contact). Ensure that planting equipment is functioning properly in accordance with manufacturing recommendations to minimize seed coat abrasion during planting to reduce dust which can drift to blooming crops or weeds.
- Do not re-use bags from treated seed to handle food or feed products.
- Dispose of seed packaging in accordance with local requirements.
- The compound is toxic to birds and mammals. Treated clothianidin seeds exposed on soil surface may be hazardous to birds and mammals. Cover or collect seeds spilled during loading.
- After seeds have been planted, do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 24 hours. Exception: Once seeds are planted and covered by soil or other planting media, the Worker Protection Standard (WPS) allows workers to enter the treated area without restriction."
- Areas planted with treated seed of barley, oats and wheat may be replanted immediately with bulb vegetables, canola, cereal grains (except rice), cotton, fruiting vegetables (including cucurbits), leafy vegetables (including brassica vegetables), rapeseed, root and tuber vegetables and soybean. These areas may also be replanted after 30 days with dry beans, grasses, non-grass animal feeds and rice. These areas may also be replanted after 8 months with sugarcane. Do not plant any other crop in the treated area for at least one year after these treated seeds are planted.

## PRODUCT INFORMATION

*NipsIt SUITE* Cereals OF Seed Protectant is a systemic fungicide plus insecticide product formulated for seed treatment use to provide protection against seed-borne and soil-borne diseases and seed protection against wireworm. The fungicide active ingredients in *NipsIt SUITE* Cereals OF Seed Protectant are metconazole, a broad-spectrum, systemic, triazole fungicide, and metalaxyl, an Oomycete-active, systemic acylalanine fungicide. The fungicide components of *NipsIt SUITE* Cereals OF Seed Protectant provide activity against *Pythium spp.*, *Rhizoctonia solani*, *Fusarium spp.*, and other Deuteromycete and Basidiomycete (smut and bunt) fungi. Clothianidin is a systemic insecticide in *NipsIt SUITE* Cereals OF Seed Protectant giving seed protection against wireworm.



## MODES OF ACTION

Metalaxyl fungicide contained in *NipsIt INSIDE* Cereals OF Seed Protectant is a member of the acylalanine chemical group (FRAC Code 4) and interrupts fungal nucleic acid synthesis. Metconazole belongs to the sterol biosynthesis inhibitor group of fungicides (FRAC Code 3). Clothianidin is a neonicotinoid insecticide (IRAC MoA Group 4A) acting as a nicotine acetylcholine receptor agonist/antagonist in insect metabolism.

## APPLICATION DIRECTIONS

Accurate application of *NipsIt SUITE* Cereals OF Seed Protectant to seed is required for control of pests. *NipsIt SUITE* Cereals OF Seed Protectant is ready to use and may be applied direct to seed as formulated. However, to enhance uniform seed coverage, dilution with water may be appropriate for some types of treaters and/or treating seed under dry and/or hot conditions. If so, mix *NipsIt SUITE* Cereals OF Seed Protectant and water thoroughly into slurry before treating seed. Recalibrate treating equipment to compensate for the addition of water. The amount of dilution water that is most suitable depends on the seed, treating equipment, and the temperature.

For preparation of product in a slurry mixture with water, use the following guideline:

<i>NipsIt SUITE</i> Cereals OF Seed Protectant Use Rate:	Amount of water to be added to product:	Total Slurry Volume to apply per cwt. seed:
5.0 fl.oz./cwt. seed	5.0 – 10 fl.oz.	10.0 – 15 fl.oz.
7.5 fl.oz./cwt. seed	7.5 fl.oz./cwt.	15 fl.oz./cwt.

Use standard slurry or mist-type seed treatment equipment.

The following tables provide use rates of *NipsIt SUITE* Cereals OF Seed Protectant by labeled crop, with disease and insect protection guidelines:

BARLEY			
Seed/Seedling Diseases	Insect Pests	<i>NipsIt SUITE</i> Cereals OF Seed Protectant Use Rates	
		fl oz/100 lbs seed	<sup>1</sup> active Ingredient (mg ai/seed)
Covered Smut Loose Smut Seed Decay Fungi Fusarium Seed Scab Pythium Seed Rot and Seedling Dieback Early Season Fusarium Seedling Dieback Early Season Rhizoctonia Root Rot Early Season Common Root Rot	Wireworm	5.0 -7.5	Clothianidin (0.00333 -0.005)  Metalaxyl (0.001 -0.0015)  Metconazole (0.00049-0.00074)
Regardless of type of application (seed treatment, soil or foliar ), do not apply more than a total of 6.4 oz (181.4 gram) active ingredient clothianidin per acre per cropping cycle.			

<sup>1</sup>mg active ingredient per seed is based on 13,605 seeds per pound



OATS			
Seed/Seedling Diseases	Insect Pests	NipsIt SUITE Cereals OF Seed Protectant Use Rates	
		fl oz/100 lbs seed	<sup>1</sup> active Ingredient (mg ai/seed )
Loose Smut Seed Decay Fungi Fusarium Seed Scab Pythium Seed Rot and Seedling Dieback Early Season Fusarium Seedling Dieback Early Season Rhizoctonia Root Rot Early Season Common Root Rot	Wireworm	5.0 -7.5	Clothianidin (0.00238 -0.00357) Metalaxyl (0.00072 -0.00107) Metconazole (0.00035-0.00053)
Regardless of type of application (seed treatment, soil or foliar ), do not apply more than a total of 6.4 oz (181.4 gram) active ingredient clothianidin per acre per cropping cycle			

<sup>1</sup> mg active ingredient per seed is based on 19,047 seeds per pound



WHEAT			
Seed/Seedling Diseases	Insect Pests	NipsIt SUITE Cereals OF Seed Protectant Use Rates	
		fl oz/100 lbs seed	<sup>1</sup> active Ingredient (mg.ai/seed)
Common Bunt Flag Smut Loose Smut Seed Decay Fungi Fusarium Seed Scab Pythium Seed Rot and Seedling Dieback Early Season Fusarium Seedling Dieback Early Season Rhizoctonia Root Rot Early Season Common Root Rot	Wireworm	5.0 -7.5	Clothianidin (0.004 -0.006mg) Metalaxyl (0.0012-0.0018 mg) Metconazole (0.00059-0.00089 mg)
Regardless of type of application (seed treatment, soil or foliar ), do not apply more than a total of 6.4 oz (181.4 gram) active ingredient clothianidin per acre per cropping cycle			

<sup>1</sup>mg active ingredient per seed is based on 11,338 seeds per pound



## STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage and disposal.

### PESTICIDE STORAGE

Store in a dry place away from excessive heat.

Do not store near food or feed.

Store in original container only.

To close package, replace and tighten cap to form an airtight seal.

### PESTICIDE DISPOSAL

To avoid wastes, use all material in this container by application according to label directions. If wastes cannot be avoided, offer remaining product to a waste facility or pesticide disposal program (often such programs are run by state or local governments or by industry).

### CONTAINER HANDLING

*[Use the following statement for containers equal to or less than 5 gallons]*

Nonrefillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container 1/4 full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Offer for recycling, if available; otherwise dispose of in a sanitary landfill or incinerator.

*[Use the following statement for containers greater than 5 gallons]*

Nonrefillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container 1/4 full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times. Offer for recycling, if available; otherwise dispose of in a sanitary landfill or incinerator.

*[Use the following statement for all formulation types/all refillable container types]*

Refillable container. Refill this container with pesticide only. Do not reuse this container for any other purpose. Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. To clean the container before final disposal, empty the remaining contents from this container into application equipment or mix tank. Fill the container about 10 percent full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this rinsing procedure two more times. Offer for recycling, if available; otherwise dispose of in a sanitary landfill or incineration.

### RECYCLING

Once cleaned, some agricultural plastic pesticide containers can be taken to a container collection site or picked up for recycling. To find the nearest site, contact your chemical dealer or manufacturer, or contact the Ag Container Recycling Council (ACRC) at 877-952-2272 (toll free) or [www.acrecycle.org](http://www.acrecycle.org).



*NipsIt* is a trademark of Valent U.S.A. Corporation

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Manufactured For:

**Valent U.S.A. Corporation**

P. O. Box 8025

Walnut Creek CA 94596-8025

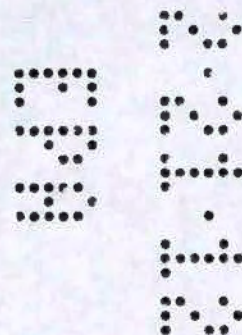
Made in U.S.A.

EPA Reg. No. 59639-183

EPA Est. No.

059639-00183.20111220.NIP.Cereal,rev1.FINAL

20111219.20111214.20110609





# Material Sent for Data Extraction

Reg. # 59639-183

Description: Amended label to add signal word CAUTION

☒ Material(s) Sent to Data Extraction Contractors:

☒ New Stamped Label Dated 5/1/2012

☐ Notification Dated \_\_\_\_\_

☐ New CSFs Dated \_\_\_\_\_

☐ Other: \_\_\_\_\_

☐ Decision #: 464265

☐ Other Action/Comments: \_\_\_\_\_

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Julie A. Chao

Phone: 308-8735 Division: RD/IRB

Date: May 1, 2012



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460



OFFICE OF  
CHEMICAL SAFETY AND  
POLLUTION PREVENTION

MAY - 1 2012

Linda Obrestad  
Green Light, A Valent U.S.A. Company  
160 Riviera Ave., Suite 200  
Walnut Creek, CA 94596-8025

Subject: Amended labeling to add the signal word CAUTION  
Product Name: NipsIt™ SUITE Cereals OF Seed Protectant  
EPA Reg. No.: 59639-183  
EPA Decision No.: 464265

Dear Ms. Obrestad:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, is acceptable. A stamped copy of the label is enclosed for your records.

Per 40 CFR §156.10(a)(6), submit one copy of your final printed labeling before you release the product for shipment. As defined in 40 CFR §152.3, "final printed labeling" means the "label or labeling of the product when distributed or sold." Clearly legible reproductions or photo reductions will be accepted for unusual labels. Note that a clean copy of the master label in most cases does not meet the definition of final printed labeling.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). If you have any questions, please contact Julie Chao by phone at: (703) 308-8735, or by email at: [chao.julie@epa.gov](mailto:chao.julie@epa.gov).

Sincerely,

A handwritten signature in blue ink that reads "Venus Eagle".

Venus Eagle, Product Manager 01  
Insecticide-Rodenticide Branch  
Registration Division (7505P)  
Office of Pesticide Programs

Enclosure: *Label Stamped "Accepted"*





## NipsIt™ SUITE Cereals OF Seed Protectant

A SEED TREATMENT PRODUCT PROVIDING SYSTEMIC SEED AND SEEDLING PROTECTION AGAINST LISTED EARLY SEASON CEREAL DISEASES AND WIREWORM

Active Ingredients	By Wt.
Clothianidin <sup>1</sup> .....	2.93%
Metalaxyl <sup>2</sup> .....	0.88%
Metconazole <sup>3</sup> .....	0.44%
Other Ingredients .....	95.75%
Total .....	100%

<sup>1</sup>(E)-1-(2-chloro-1,3-thiazol-5-ylmethyl)-3-methyl-2-nitroguanidine

<sup>2</sup>N-(2,6-dimethylphenyl)-N-(methoxyacetyl)alanine methyl ester

<sup>3</sup>5-[(4-chlorophenyl)methyl]-2,2-dimethyl-1-(1H-1,2,4-triazol-1-ylmethyl)cyclopentanol

One gallon of *NipsIt SUITE Cereals OF Seed Protectant* contains 0.256 lbs clothianidin, 0.077 lbs metalaxyl, and 0.038 lbs metconazole.

**KEEP OUT OF REACH OF CHILDREN**

### CAUTION

SEE NEXT PAGE FOR PRECAUTIONARY STATEMENTS

#### NET CONTENTS

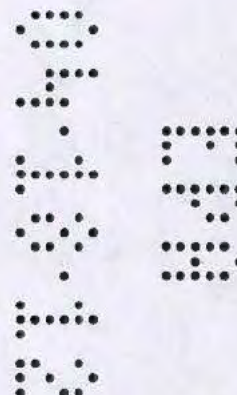
EPA Reg. No. 59639-183  
EPA Est. No.

ACCEPTED

MAY - 1 2012

Under the Federal Insecticide, Fungicide,  
and Rodenticide Act, as amended, for the  
pesticide registered under:

EPA. Reg. No: 59639-183





# **PRECAUTIONARY STATEMENTS**

## **HAZARDS TO HUMANS & DOMESTIC ANIMALS**

### **CAUTION**

**PERSONAL PROTECTIVE EQUIPMENT (PPE):** Mixers, loaders, applicators and other handlers must wear: Long-sleeved shirt and long pants, chemical resistant gloves made of any waterproof material, socks and shoes.

Follow the manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry.

#### **USER SAFETY RECOMMENDATIONS**

Users should:

- Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.
- Remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

#### **ENVIRONMENTAL HAZARDS**

This product is toxic to aquatic invertebrates. Do not apply directly to water or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment wash water or rinsate. Do not apply where runoff is likely to occur. Drift and runoff may be hazardous to aquatic organisms in water adjacent to treated areas. Apply this product only as specified on label.

Treated seed exposed on soil surface maybe hazardous to birds. Cover or collect spilled seeds.

Metalaxyl has properties and characteristics associated with chemicals detected in ground water. This chemical may leach into ground water if used in areas where soils are permeable, particularly where the water table is shallow. Therefore, contain any product spills or equipment leaks and dispose of waste according to the disposal instructions on this label.

#### **DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

**READ ENTIRE LABEL. USE STRICTLY IN ACCORDANCE WITH PRECAUTIONARY STATEMENTS AND DIRECTIONS AND WITH APPLICABLE STATE AND FEDERAL REGULATIONS.**

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the State or Tribal agency responsible for pesticide regulation.



### AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR Part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted-entry interval. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the **restricted entry interval (REI) of 24 hours**.

**Exception:** Once the seeds are planted in soil, the Worker Protection Standard, under certain circumstances, allows workers to enter the treated area without restriction if there will be no worker contact with the soil subsurface or treated seed. PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is: long-sleeved shirt and long pants; chemical-resistant gloves such as barrier laminate, butyl rubber, nitrile rubber, or Viton; shoes plus socks.



**DISCLAIMER, RISKS OF USING THIS PRODUCT,  
LIMITED WARRANTY  
AND LIMITATION OF LIABILITY**

**IMPORTANT:** Read the entire Label including this Disclaimer, Risks of Using this Product, Limited Warranty, and Limitation of Liability before using this product. If the terms are not acceptable THEN DO NOT USE THE PRODUCT; rather, return the unopened product within 15 days of purchase for a refund of the purchase price.

**ASSUMPTION OF RISK**

The Buyer and User (referred to collectively herein as "Buyer") of this product should be aware that there are inherent unintended risks associated with the use of this product which are impossible to eliminate. These risks include, but are not limited to, injury to plants and crops to which this product is applied, lack of control of the target pests to this product. Such risks of crop injury, non-performance, or other unintended consequences are unavoidable and may result because of such factors as weather, soil conditions, disease, moisture conditions, irrigation practices, cultural practices or the manner of use or application, (or a combination of such factors) all of which are factors beyond the control of Valent. The Buyer should be aware that these inherent unintended risks may reduce the harvested yield of the crop in all or a portion of the treated acreage, or otherwise affect the crop such that additional care, treatment and expense are required to take the crop to harvest. If the Buyer chooses not to accept these risks, THEN THIS PRODUCT SHOULD NOT BE APPLIED. By applying this product Buyer acknowledges and accepts these inherent unintended risks AND TO THE FULLEST EXTENT ALLOWED BY LAW, AGREES THAT ALL SUCH RISKS ASSOCIATED WITH THE APPLICATION AND USE ARE ASSUMED BY THE BUYER.

Valent shall not be responsible for losses or damages (including, but not limited to, loss of yield, increased expenses of farming the crop or such incidental, consequential or special damages that may be claimed) resulting from use of this product in any manner not set forth on the label. Buyer assumes all risks associated with the use of this product in any manner or under conditions not specifically directed or approved on the label.

**LIMITED WARRANTY**

Valent warrants only that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated in the label, under average use conditions, when used strictly in accordance with the label and subject to the Risks of Using This Product as described above. To the extent consistent with applicable law AND AS SET FORTH ABOVE, VALENT MAKES NO OTHER WARRANTIES, EITHER EXPRESSED OR IMPLIED. No agent or representative of Valent or Seller is authorized to make or create any other express or implied warranty.

**LIMITATION OF LIABILITY**

To the fullest extent allowed by law, Valent or Seller is not liable for any incidental, consequential, indirect or special damages resulting from the use or handling of this product. The limitation includes, but is not limited to, loss of yield on all or any portion of the treated acreage, increased care, treatment or other expenses required to take the crop to harvest, increased finance charges or altered finance ratings, emotional or mental distress and/or exemplary damages. TO THE FULLEST EXTENT ALLOWED BY LAW, THE EXCLUSIVE REMEDY OF THE BUYER, AND THE EXCLUSIVE MAXIMUM LIABILITY OF VALENT OR SELLER FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OF WARRANTY, CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE) RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT SHALL BE THE RETURN OF THE PURCHASE PRICE OF THIS PRODUCT OR, AT THE ELECTION OF VALENT OR SELLER, THE REPLACEMENT OF THE PRODUCT.

**PROMPT NOTICE OF CLAIM**

To the extent consistent with applicable law allowing such requirements Valent must be provided notice as soon as Buyer has reason to believe it may have a claim, but in no event later than twenty-one days from date of planting, or twenty-one days from the date of application, whichever is latter, so that an immediate inspection of the affected property and growing crops can be made.

To the extent consistent with applicable law if Buyer does not notify Valent of any claims, in such period, it shall be barred from obtaining any remedy.

**NO AMENDMENTS**

Valent and Seller offer this product, and Buyer accepts it, subject to the foregoing Disclaimer, Risks of Using This Product, Limited Warranty and Limitation of Liability, which may not be modified by any oral or written agreement.



## RESISTANCE MANAGEMENT

*NipsIt SUITE* Cereals OF Seed Protectant contains Clothianidin which is a neonicotinoid and a Group 4A insecticide. Insect biotypes with acquired resistance to Group 4A insecticides may eventually dominate the insect population if Group 4A insecticides are used repeatedly in the same field or in successive years as the primary method of control for targeted species. This may result in partial or total loss of control of those species by *NipsIt SUITE* Cereals OF Seed Protectant or other Group 4A insecticides. Valent U.S.A. Corporation strives to maintain strong stewardship of this product by recommending that its use be coordinated in a planned resistance management strategy program established for the specific crop and area.

Contact your local extension specialist, certified crop advisors and/or manufacturer for insecticide resistance management or IPM recommendations for the specific site and resistant pest problems.

For further information or to report suspected resistance, you may contact Valent U.S.A. Corporation at 800-682-5368.

## PRECAUTIONS AND RESTRICTIONS

*NipsIt SUITE* Cereals OF Seed Protectant is formulated as a ready-to-use seed protectant formulation and must be used only in accordance with specifications on this label utilizing mechanical, slurry, or mist-type seed treating equipment, provided that the equipment can be calibrated to accurately and uniformly apply the product to seed. This product is for both commercial and on-farm application. Do not use planter box or hopper box when applying product to seeds. Always mix product thoroughly before use.

As stated by regulations specified in 40 CFR 153.155, all seed treated with *NipsIt SUITE* Cereals OF Seed Protectant must be colored with an EPA-approved dye or colorant to visually distinguish seed that is treated with a pesticide. This product contains such dye or colorant. This regulation is necessary to prevent treated seed from accidental use as a food for man or feed for animals.

### Seed Quality and Storage of Treated Seed

Seed treatments applied to low vigor or poor quality seed or to mechanically damaged seed may result in loss of seed germination or reduced seedling vigor. To verify seed safety, treat a small portion of seed prior to treatment of an entire seed lot. Utilize standard seed germination methodologies to determine and verify seed safety. Proper storage conditions of treated seed are recommended. Due to seed quality and seed storage conditions beyond the control of Valent U.S.A. Corporation, no claims are made to guarantee the germination of carry-over treated seed.

## SEED BAG TAG

The Federal Seed Act requires that the container of seed treated with *NipsIt SUITE* Cereals OF Seed Protectant containing clothianidin, metalaxyl, and metconazole must be labeled with the following statements:

- This seed has been treated with *NipsIt SUITE* Cereals OF Seed Protectant which contains clothianidin, metalaxyl and metconazole.
- Do not use treated seed for feed, food or oil processing.



In addition, the U.S. Environmental Protection Agency requires the following statements on the container of seed treated with *NipsIt SUITE Cereals OF Seed Protectant*:

- Regardless of the type of application (seed treatment, soil or foliar), do not apply more than a total of 6.4 oz (181.4 gram) clothianidin (active ingredient) per acre per cropping cycle.
- Store away from feeds and other foodstuffs.
- Excess treated seed may be used for ethanol production only if (1) by-products are not used for livestock feed and (2) no measurable residues of pesticide remain in ethanol by-products that are used in agronomic practice.
- Wear long sleeved shirt, long pants and chemical resistant gloves when handling treated seed.
- Dispose of all excess treated seed. Left over treated seed may be double-sown around the headland or buried away from water sources in accordance with local requirements. Do not contaminate water bodies when disposing of planting equipment washwaters.
- Treated seeds must be planted at a minimum depth of 0.5 inch.
- This compound is toxic to birds and mammals. Treated clothianidin seeds exposed on soil surface may be hazardous to birds and mammals. Cover or collect seeds spilled during loading.
- This compound is highly toxic to bees exposed directly (contact). Ensure that planting equipment is functioning properly in accordance with manufacturing recommendations to minimize seed coat abrasion during planting to reduce dust which can drift to blooming crops or weeds.
- Do not re-use bags from treated seed to handle food or feed products.
- Dispose of seed packaging in accordance with local requirements.
- The compound is toxic to birds and mammals. Treated clothianidin seeds exposed on soil surface may be hazardous to birds and mammals. Cover or collect seeds spilled during loading.
- After seeds have been planted, do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 24 hours. Exception: Once seeds are planted and covered by soil or other planting media, the Worker Protection Standard (WPS) allows workers to enter the treated area without restriction."
- Areas planted with treated seed of barley, oats and wheat may be replanted immediately with bulb vegetables, canola, cereal grains (except rice), cotton, fruiting vegetables (including cucurbits), leafy vegetables (including brassica vegetables), rapeseed, root and tuber vegetables and soybean. These areas may also be replanted after 30 days with dry beans, grasses, non-grass animal feeds and rice. These areas may also be replanted after 8 months with sugarcane. Do not plant any other crop in the treated area for at least one year after these treated seeds are planted.

## PRODUCT INFORMATION

*NipsIt SUITE Cereals OF Seed Protectant* is a systemic fungicide plus insecticide product formulated for seed treatment use to provide protection against seed-borne and soil-borne diseases and seed protection against wireworm. The fungicide active ingredients in *NipsIt SUITE Cereals OF Seed Protectant* are metconazole, a broad-spectrum, systemic, triazole fungicide, and metalaxyl, an Oomycete-active, systemic acylalanine fungicide. The fungicide components of *NipsIt SUITE Cereals OF Seed Protectant* provide activity against *Pythium spp.*, *Rhizoctonia solani*, *Fusarium spp.*, and other Deuteromycete and Basidiomycete (smut and bunt) fungi. Clothianidin is a systemic insecticide in *NipsIt SUITE Cereals OF Seed Protectant* giving seed protection against wireworm.



## MODES OF ACTION

Metalaxyl fungicide contained in *NipsIt INSIDE* Cereals OF Seed Protectant is a member of the acylalanine chemical group (FRAC Code 4) and interrupts fungal nucleic acid synthesis. Metconazole belongs to the sterol biosynthesis inhibitor group of fungicides (FRAC Code 3). Clothianidin is a neonicotinoid insecticide (IRAC MoA Group 4A) acting as a nicotine acetylcholine receptor agonist/antagonist in insect metabolism.

## APPLICATION DIRECTIONS

Accurate application of *NipsIt SUITE* Cereals OF Seed Protectant to seed is required for control of pests. *NipsIt SUITE* Cereals OF Seed Protectant is ready to use and may be applied direct to seed as formulated. However, to enhance uniform seed coverage, dilution with water may be appropriate for some types of treaters and/or treating seed under dry and/or hot conditions. If so, mix *NipsIt SUITE* Cereals OF Seed Protectant and water thoroughly into slurry before treating seed. Recalibrate treating equipment to compensate for the addition of water. The amount of dilution water that is most suitable depends on the seed, treating equipment, and the temperature.

For preparation of product in a slurry mixture with water, use the following guideline:

<i>NipsIt SUITE</i> Cereals OF Seed Protectant Use Rate:	Amount of water to be added to product:	Total Slurry Volume to apply per cwt. seed:
5.0 fl.oz./cwt. seed	5.0 – 10 fl.oz.	10.0 – 15 fl.oz.
7.5 fl.oz./cwt. seed	7.5 fl.oz./cwt.	15 fl.oz./cwt.

Use standard slurry or mist-type seed treatment equipment.

The following tables provide use rates of *NipsIt SUITE* Cereals OF Seed Protectant by labeled crop, with disease and insect protection guidelines:

BARLEY			
Seed/Seedling Diseases	Insect Pests	<i>NipsIt SUITE</i> Cereals OF Seed Protectant Use Rates	
		fl oz/100 lbs seed	<sup>1</sup> active Ingredient (mg ai/seed)
Covered Smut Loose Smut Seed Decay Fungi Fusarium Seed Scab Pythium Seed Rot and Seedling Dieback Early Season Fusarium Seedling Dieback Early Season Rhizoctonia Root Rot Early Season Common Root Rot	Wireworm	5.0 -7.5	Clothianidin (0.00333 -0.005)  Metalaxyl (0.001 -0.0015)  Metconazole (0.00049-0.00074)
Regardless of type of application (seed treatment, soil or foliar ), do not apply more than a total of 6.4 oz (181.4 gram) active ingredient clothianidin per acre per cropping cycle.			

<sup>1</sup>mg active ingredient per seed is based on 13,605 seeds per pound



OATS			
Seed/Seedling Diseases	Insect Pests	NipsIt SUITE Cereals OF Seed Protectant Use Rates	
		fl oz/100 lbs seed	<sup>1</sup> active Ingredient (mg ai/seed )
Loose Smut Seed Decay Fungi Fusarium Seed Scab Pythium Seed Rot and Seedling Dieback Early Season Fusarium Seedling Dieback Early Season Rhizoctonia Root Rot Early Season Common Root Rot	Wireworm	5.0 -7.5	Clothianidin (0.00238 -0.00357)  Metalaxyl (0.00072 -0.00107)  Metconazole (0.00035-0.00053)
Regardless of type of application (seed treatment, soil or foliar ), do not apply more than a total of 6.4 oz (181.4 gram) active ingredient clothianidin per acre per cropping cycle			

<sup>1</sup> mg active ingredient per seed is based on 19,047 seeds per pound



WHEAT			
Seed/Seedling Diseases	Insect Pests	NipsIt SUITE Cereals OF Seed Protectant Use Rates	
		fl oz/100 lbs seed	<sup>1</sup> active Ingredient (mg.ai/seed)
Common Bunt Flag Smut Loose Smut Seed Decay Fungi Fusarium Seed Scab Pythium Seed Rot and Seedling Dieback Early Season Fusarium Seedling Dieback Early Season Rhizoctonia Root Rot Early Season Common Root Rot	Wireworm	5.0 -7.5	Clothianidin (0.004 -0.006mg)  Metalaxyl (0.0012 -0.0018 mg)  Metconazole (0.00059-0.00089 mg)
Regardless of type of application (seed treatment, soil or foliar ), do not apply more than a total of 6.4 oz (181.4 gram) active ingredient clothianidin per acre per cropping cycle			

<sup>1</sup> mg active ingredient per seed is based on 11,338 seeds per pound



## **STORAGE AND DISPOSAL**

Do not contaminate water, food or feed by storage and disposal.

### **PESTICIDE STORAGE**

Store in a dry place away from excessive heat.

Do not store near food or feed.

Store in original container only.

To close package, replace and tighten cap to form an airtight seal.

### **PESTICIDE DISPOSAL**

To avoid wastes, use all material in this container by application according to label directions. If wastes cannot be avoided, offer remaining product to a waste facility or pesticide disposal program (often such programs are run by state or local governments or by industry).

### **CONTAINER HANDLING**

*[Use the following statement for containers equal to or less than 5 gallons]*

Nonrefillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container 1/4 full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Offer for recycling, if available; otherwise dispose of in a sanitary landfill or incinerator.

*[Use the following statement for containers greater than 5 gallons]*

Nonrefillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container 1/4 full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times. Offer for recycling, if available; otherwise dispose of in a sanitary landfill or incinerator.

*[Use the following statement for all formulation types/all refillable container types]*

Refillable container. Refill this container with pesticide only. Do not reuse this container for any other purpose. Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. To clean the container before final disposal, empty the remaining contents from this container into application equipment or mix tank. Fill the container about 10 percent full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this rinsing procedure two more times. Offer for recycling, if available; otherwise dispose of in a sanitary landfill or incineration.

### **RECYCLING**

Once cleaned, some agricultural plastic pesticide containers can be taken to a container collection site or picked up for recycling. To find the nearest site, contact your chemical dealer or manufacturer, or contact the Ag Container Recycling Council (ACRC) at 877-952-2272 (toll free) or [www.acrecycle.org](http://www.acrecycle.org).



*NipsIt* is a trademark of Valent U.S.A. Corporation

Copyright© 2012 by Valent U.S.A. Corporation

Manufactured For:

**Valent U.S.A. Corporation**

P. O. Box 8025

Walnut Creek CA 94596-8025

Made in U.S.A.

EPA Reg. No. 59639-183

EPA Est. No.

059639-00183.20120417.NIP.signalword

20111220.NIP.Cereal,rev1.FINAL



# FAST-TRACK AMENDMENTS – Completeness Screening Checklist

Expert's In-Processing Signature: Schaible Date: 4/26/12 PM #: 61

EPA Reg. Number: <u>59639-183</u>	EPA Receipt Date: <u>4/18/12</u>
-----------------------------------	----------------------------------

	Checklist Item	Yes	No	N/A
1	<b>Application Form</b> (EPA Form 8570-1) - signed?	✓		
2	<b>Confidential Statement of Formula</b> (EPA Form 8570-29) - signed?			✓
3	<b>Certification with Respect to Citation of Data</b> (EPA Form 8570-34) - signed?			✓
4	<b>Formulator's Exemption Statement</b> (EPA Form 8570-27) - signed?			✓
5	<b>Data Matrix</b> (EPA Form 8570-35) [Applicable for adding me-too uses] - signed?			✓
	a) Selective Method?			
	b) Cite-All Method?			
	c) Public copy of Matrix provided? See PR Notice 98-5			
6	<b>Is Label included?</b> (5 copies)	✓		
	a) Electronic Label submitted?	✓		
	<b>Comments:</b>			



**Receipt for Section 3**

S: 915446

Resubmission: ☐ Yes ☒ No

Regulatory Type: Product Registration - Section 3

Fee For Service: ☐ Yes ☒ No

Application Type: Amendment

Billable: ☐ Yes ☒ No

Company: 59639 VALENT U.S.A. CORPORATION

V

Risk Manager: Registration Division, Risk Management Team 1

Product #: 59639-183

Product Name: NIPSIT SUITE CEREALS OF SEED PROTECTAI

Override#:

Me Too Section3:

Me Too Product Name:

Application Date: 17-Apr-2012

OPP Rec'd Date: 18-Apr-2012

Front End Date: 18-Apr-2012

Risk Manager Send Date: 19-Apr-2012

FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

Label amendment

Form A: ☐

Signature Date:

Form B: ☐

Signature Date:

New Ingredient Request Date:

New Ingredient Received Date:

View/Edit

Print Letter

Enter More Information

Tracking

Receipt Content	Des
Paper Label	
Electronic Label	





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

April 25, 2012

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

DANIEL P. FAY  
VALENT U.S.A. CORPORATION  
1600 RIVIERA AVENUE, SUITE 200  
WALNUT CREEK, CA 94596

PRODUCT NAME: NIPSIT SUITE CEREALS OF SEED PROTECTANT  
COMPANY NAME: VALENT U.S.A. CORPORATION  
OPP IDENTIFICATION NUMBER:  
EPA FILE SYMBOL: 59639-183  
EPA RECEIPT DATE: 04/18/12

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application appears to qualify for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability for fast track status.

If you have any questions, please contact Registration Division, Risk Management Team 1, at (703) 308-8045.

Sincerely,

A handwritten signature in black ink, appearing to be "Suf".

Front End Processing Staff  
Information Services Branch  
Information Technology & Resources Management Division



# Fee for Service

{9154466~

This package includes the following

☐ New Registration

☒ Amendment

☐ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: \_\_\_\_

for Division

☐ AD

☐ BPPD

☒ RD

Risk Mgr.

Receipt No.

S-

EPA File Symbol/Reg. No.

Pin-Punch Date:



This item is NOT subject to FFS action.

## Action Code:

Requested:

Granted:

Amount Due: \$

## Parent/Child Decisions:

☒ Inert Cleared for Intended Use



Uncleared Inert in Product

Reviewer: Steve Schaub

Date: 4/19/12

Remarks:





United States  
Environmental Protection Agency  
Washington, DC 20460

☐ Registration  
☒ Amendment  
☐ Other

OPP Identifier Number

## Application for Pesticide - Section I

1. Company/Product Number 59639-183	2. EPA Product Manager Ms. Venus Eagle	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) NipsIt SUITE Cereals OF Seed Protectant	PM# 01	
5. Name and Address of Applicant (Include ZIP Code) Green Light, A Valent U.S.A. Company 1600 Riviera Ave., Suite 200 Walnut Creek, CA 94596-8025 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

## Section - II

<input checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Fast Track Amendment: Addition of the signal word CAUTION.

## Section - III

1. Material This Product Will Be Packaged In:					
Child-Resistant Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container QT		5. Location of Label Directions <input checked="" type="checkbox"/> On Labeling	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

## Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Linda Obrestad	Title Regulatory Analyst	Telephone No. (Include Area Code) 925-256-2791	
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped)
2. Signature 	3. Title Regulatory Analyst		
4. Typed Name Linda Obrestad	5. Date April 17, 2012		





April 17, 2012

**NipsIt™ SUITE Cereals OF Seed Protectant**  
**EPA Reg. No. 59639-183**  
**FAST TRACK AMENDMENT**

Ms. Venus Eagle (PM 1)  
Insecticide-Rodenticide Branch  
Document Processing Deck (AMEND)  
Office of Pesticide Programs  
U.S. Environmental Protection Agency (7505P)  
Room S-4900, One Potomac Yard  
2777 S. Crystal Drive  
Arlington, VA 22202

Dear Ms. Eagle:

Valent U.S.A. Company is respectfully submitting this Fast Track Amendment to update our product label NipsIt™ SUITE Cereals OF Seed Protectant (EPA Reg. No. 59639-183). This proposed labeling is adding the signal word "CAUTION". Valent has been requested by a state agency to add a signal word to the label for their training purposes. The toxicity six-pack reports were a category IV and we are not required to show a signal word on the label. Valent would like to comply with this state request.

I have enclosed the following documents to support this Fast Track Label Amendment submission:

- Pesticide application (Form 8570-1)
- Five (5) copies of the proposed label
- One (1) courtesy copy of the proposed label with redline additions
- A CD with the proposed label in pdf format
- A Certification Statement with Respect to Label Integrity

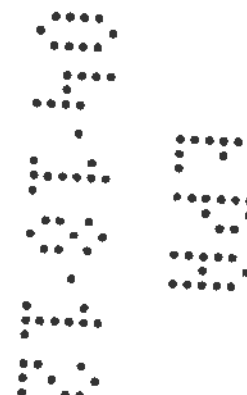
If you should have any questions please contact me at (925) 256-2791 or email: [linda.obrestad@valent.com](mailto:linda.obrestad@valent.com) or Ms. Sue Shen at (972) 244-6543 or email: [sshen@valent.com](mailto:sshen@valent.com).

Sincerely,

A handwritten signature in blue ink that reads "Linda Obrestad". The signature is fluid and cursive, with the first name "Linda" and last name "Obrestad" clearly distinguishable.

Linda Obrestad  
Regulatory Analyst  
Registration and Regulatory Affairs

Enclosures







# Certification with Respect to Label Integrity

version: 9/11/02

I certify that the information (including, but not limited to, text, tables, and graphics) contained in the electronic file identified below by file name and submitted with this certification is the same information as that on the paper copies of these documents included with this submission.

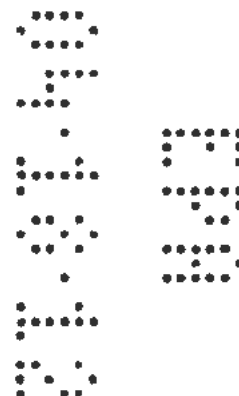
PROPOSED LABEL		
EPA Registration #	Date Submitted to EPA	Electronic file name
59639-183	20120417	059639-00183.20120417.NIP.signalword.pdf

I certify that the statements that I have made on this form are true, accurate, and complete. I acknowledge that any knowingly false or misleading statements may be punishable by fine or imprisonment or both under applicable law.

*Linda Obrestad*  
Signature

April 17, 2012  
Date

Linda Obrestad  
Regulatory Analyst  
Registration and Regulatory Affairs  
Valent U.S.A. Corporation





## Material Sent for Data Extraction

Reg. # 59639-183

Description: Agency ltr 12/21/11, accept label 12/21/11, emails (12, 9/11, 12/20/11), acute tox 12/6/11, pc 12/5/11, front office ltrs 7/6/11 & 6/17/11, reg ltr 6/16/11, front end ltr 6/13/11, 21 day screen 6/10/11, reg ltr 6/9/11, 8570-1 6/9/11, 8570-27 6/6/11, 8570-34 6/9/11, online payment 6/6/11, data matrix 6/9/11 MSDS 6/2/11

### ☒ Material(s) Sent to Data Extraction Contractors:

- ☒ New Stamped Label Dated 12/21/11
- ☐ Notification Dated \_\_\_\_\_
- ☒ New CSF(s) Dated 6/15/11
- ☒ Other: AGENCY LTR 12/21/11

☐ Decision #: \_\_\_\_\_

☐ Other Action/Comments: \_\_\_\_\_

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Marianne Lewis

Phone: 308-8043 Division: IRB/RD

Date: 12/21/11





## U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs  
Registration Division (7505C)  
1200 Pennsylvania Ave., N.W.  
Washington, D.C. 20460

EPA Reg. Number:

59639-183

Date of Issuance:

DEC 21 2011

## NOTICE OF PESTICIDE:

☒ Registration  
☐ Reregistration  
(under FIFRA, as amended)

Term of Issuance:

Unconditional

Name of Pesticide Product:

NipsIt SUITE Cereals OF Seed  
Protectant

## Name and Address of Registrant (include ZIP Code):

Valent U.S.A. Corp.  
P.O. Box 8025 1600 RIVIERA AVE., SUITE 200  
Walnut Creek, CA 94596-8025

**Note:** Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is unconditionally registered in accordance with FIFRA section 3(c)(7)(A) provided that you:

1. The data requirements for storage stability and corrosion characteristics (Guidelines 830.6317 and 830.6320) are not satisfied. A one year study is required to satisfy these data requirements. You have 18 months from the date of registration to provide these data.
2. Submit 2 copies of your final printed label before release for shipment.
3. For future submissions, make the following changes to your Confidential Statement of Formulation (EPA Form 8570-4):

- a. Box 4: Revise the EPA Reg. No. so it reads, "EPA Reg. No. 59639-183."

*continued on page 2*

Signature of Approving Official:

Venus Eagle, Product Manager 01  
Insecticide-Rodenticide Branch, Registration Division (7505P)

Date:

DEC 21 2011

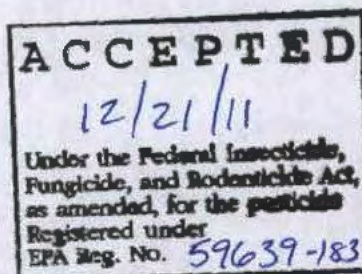


If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records. If you have any questions, please contact Marianne Lewis at 703-308-8043 or [lewis.marianne@epa.gov](mailto:lewis.marianne@epa.gov).

Venus Eagle  
Product Manager, 01  
Insecticide-Rodenticide Branch  
Registration Division (7505P)

Enclosure





## NipsIt™ SUITE Cereals OF Seed Protectant

A SEED TREATMENT PRODUCT PROVIDING SYSTEMIC SEED AND SEEDLING PROTECTION AGAINST LISTED EARLY SEASON CEREAL DISEASES AND WIREWORM

Active Ingredients	By Wt.
Clothianidin <sup>1</sup> .....	2.93%
Metalaxyl <sup>2</sup> .....	0.88%
Metconazole <sup>3</sup> .....	0.44%
Other Ingredients.....	95.75%
Total.....	100%

<sup>1</sup>(E)-1-(2-chloro-1,3-thiazol-5-ylmethyl)-3-methyl-2-nitroguanidine

<sup>2</sup>N-(2,6-dimethylphenyl)-N-(methoxyacetyl)alanine methyl ester

<sup>3</sup>5-[(4-chlorophenyl)methyl]-2,2-dimethyl-1-(1H-1,2,4-triazol-1-ylmethyl)cyclopentanol

One gallon of NipsIt SUITE Cereals OF Seed Protectant contains 0.256 lbs clothianidin, 0.077 lbs metalaxyl, and 0.038 lbs metconazole.

**KEEP OUT OF REACH OF CHILDREN**

**SEE NEXT PAGE FOR PRECAUTIONARY STATEMENTS**

### NET CONTENTS

EPA Reg. No. 59639-183

EPA Est. No.



## PRECAUTIONARY STATEMENTS

### HAZARDS TO HUMANS & DOMESTIC ANIMALS

#### PERSONAL PROTECTIVE EQUIPMENT (PPE):

**Mixers, loaders, applicators and other handlers must wear:** Long-sleeved shirt and long pants, chemical resistant gloves made of any waterproof material, socks and shoes.

Follow the manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry.

#### USER SAFETY RECOMMENDATIONS

Users should:

- Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.
- Remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

### ENVIRONMENTAL HAZARDS

This product is toxic to aquatic invertebrates. Do not apply directly to water or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment wash water or rinsate. Do not apply where runoff is likely to occur. Drift and runoff may be hazardous to aquatic organisms in water adjacent to treated areas. Apply this product only as specified on label.

Treated seed exposed on soil surface maybe hazardous to birds. Cover or collect spilled seeds.

Metalaxyl has properties and characteristics associated with chemicals detected in ground water. This chemical may leach into ground water if used in areas where soils are permeable, particularly where the water table is shallow. Therefore, contain any product spills or equipment leaks and dispose of waste according to the disposal instructions on this label.

### DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

**READ ENTIRE LABEL. USE STRICTLY IN ACCORDANCE WITH PRECAUTIONARY STATEMENTS AND DIRECTIONS AND WITH APPLICABLE STATE AND FEDERAL REGULATIONS.**

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the State or Tribal agency responsible for pesticide regulation.



### AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR Part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted-entry interval. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the **restricted entry interval (REI) of 24 hours**.

**Exception:** Once the seeds are planted in soil, the Worker Protection Standard, under certain circumstances, allows workers to enter the treated area without restriction if there will be no worker contact with the soil subsurface or treated seed. PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is: long-sleeved shirt and long pants; chemical-resistant gloves such as barrier laminate, butyl rubber, nitrile rubber, or Viton; shoes plus socks.



**DISCLAIMER, RISKS OF USING THIS PRODUCT,  
LIMITED WARRANTY  
AND LIMITATION OF LIABILITY**

**IMPORTANT:** Read the entire Label including this Disclaimer, Risks of Using this Product, Limited Warranty, and Limitation of Liability before using this product. If the terms are not acceptable THEN DO NOT USE THE PRODUCT; rather, return the unopened product within 15 days of purchase for a refund of the purchase price.

**ASSUMPTION OF RISK**

The Buyer and User (referred to collectively herein as "Buyer") of this product should be aware that there are inherent unintended risks associated with the use of this product which are impossible to eliminate. These risks include, but are not limited to, injury to plants and crops to which this product is applied, lack of control of the target pests to this product. Such risks of crop injury, non-performance, or other unintended consequences are unavoidable and may result because of such factors as weather, soil conditions, disease, moisture conditions, irrigation practices, cultural practices or the manner of use or application, (or a combination of such factors) all of which are factors beyond the control of Valent. The Buyer should be aware that these inherent unintended risks may reduce the harvested yield of the crop in all or a portion of the treated acreage, or otherwise affect the crop such that additional care, treatment and expense are required to take the crop to harvest. If the Buyer chooses not to accept these risks, THEN THIS PRODUCT SHOULD NOT BE APPLIED. By applying this product Buyer acknowledges and accepts these inherent unintended risks AND TO THE FULLEST EXTENT ALLOWED BY LAW, AGREES THAT ALL SUCH RISKS ASSOCIATED WITH THE APPLICATION AND USE ARE ASSUMED BY THE BUYER.

Valent shall not be responsible for losses or damages (including, but not limited to, loss of yield, increased expenses of farming the crop or such incidental, consequential or special damages that may be claimed) resulting from use of this product in any manner not set forth on the label. Buyer assumes all risks associated with the use of this product in any manner or under conditions not specifically directed or approved on the label.

**LIMITED WARRANTY**

Valent warrants only that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated in the label, under average use conditions, when used strictly in accordance with the label and subject to the Risks of Using This Product as described above. To the extent consistent with applicable law AND AS SET FORTH ABOVE, VALENT MAKES NO OTHER WARRANTIES, EITHER EXPRESSED OR IMPLIED. No agent or representative of Valent or Seller is authorized to make or create any other express or implied warranty.

**LIMITATION OF LIABILITY**

To the fullest extent allowed by law, Valent or Seller is not liable for any incidental, consequential, indirect or special damages resulting from the use or handling of this product. The limitation includes, but is not limited to, loss of yield on all or any portion of the treated acreage, increased care, treatment or other expenses required to take the crop to harvest, increased finance charges or altered finance ratings, emotional or mental distress and/or exemplary damages. TO THE FULLEST EXTENT ALLOWED BY LAW, THE EXCLUSIVE REMEDY OF THE BUYER, AND THE EXCLUSIVE MAXIMUM LIABILITY OF VALENT OR SELLER FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OF WARRANTY, CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE) RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT SHALL BE THE RETURN OF THE PURCHASE PRICE OF THIS PRODUCT OR, AT THE ELECTION OF VALENT OR SELLER, THE REPLACEMENT OF THE PRODUCT.

**PROMPT NOTICE OF CLAIM**

To the extent consistent with applicable law allowing such requirements Valent must be provided notice as soon as Buyer has reason to believe it may have a claim, but in no event later than twenty-one days from date of planting, or twenty-one days from the date of application, whichever is latter, so that an immediate inspection of the affected property and growing crops can be made.

To the extent consistent with applicable law if Buyer does not notify Valent of any claims, in such period, it shall be barred from obtaining any remedy.

**NO AMENDMENTS**

Valent and Seller offer this product, and Buyer accepts it, subject to the foregoing Disclaimer, Risks of Using This Product, Limited Warranty and Limitation of Liability, which may not be modified by any oral or written agreement.



## RESISTANCE MANAGEMENT

*NipsIt SUITE* Cereals OF Seed Protectant contains Clothianidin which is a neonicotinoid and a Group 4A insecticide. Insect biotypes with acquired resistance to Group 4A insecticides may eventually dominate the insect population if Group 4A insecticides are used repeatedly in the same field or in successive years as the primary method of control for targeted species. This may result in partial or total loss of control of those species by *NipsIt SUITE* Cereals OF Seed Protectant or other Group 4A insecticides. Valent U.S.A. Corporation strives to maintain strong stewardship of this product by recommending that its use be coordinated in a planned resistance management strategy program established for the specific crop and area.

Contact your local extension specialist, certified crop advisors and/or manufacturer for insecticide resistance management or IPM recommendations for the specific site and resistant pest problems.

For further information or to report suspected resistance, you may contact Valent U.S.A. Corporation at 800-682-5368.

## PRECAUTIONS AND RESTRICTIONS

*NipsIt SUITE* Cereals OF Seed Protectant is formulated as a ready-to-use seed protectant formulation and must be used only in accordance with specifications on this label utilizing mechanical, slurry, or mist-type seed treating equipment, provided that the equipment can be calibrated to accurately and uniformly apply the product to seed. This product is for both commercial and on-farm application. Do not use planter box or hopper box when applying product to seeds. Always mix product thoroughly before use.

As stated by regulations specified in 40 CFR 153.155, all seed treated with *NipsIt SUITE* Cereals OF Seed Protectant must be colored with an EPA-approved dye or colorant to visually distinguish seed that is treated with a pesticide. This product contains such dye or colorant. This regulation is necessary to prevent treated seed from accidental use as a food for man or feed for animals.

## Seed Quality and Storage of Treated Seed

Seed treatments applied to low vigor or poor quality seed or to mechanically damaged seed may result in loss of seed germination or reduced seedling vigor. To verify seed safety, treat a small portion of seed prior to treatment of an entire seed lot. Utilize standard seed germination methodologies to determine and verify seed safety. Proper storage conditions of treated seed are recommended. Due to seed quality and seed storage conditions beyond the control of Valent U.S.A. Corporation, no claims are made to guarantee the germination of carry-over treated seed.

## SEED BAG TAG

The Federal Seed Act requires that the container of seed treated with *NipsIt SUITE* Cereals OF Seed Protectant containing clothianidin, metalaxyl, and metconazole must be labeled with the following statements:

- This seed has been treated with *NipsIt SUITE* Cereals OF Seed Protectant which contains clothianidin, metalaxyl and metconazole.
- Do not use treated seed for feed, food or oil processing.



In addition, the U.S. Environmental Protection Agency requires the following statements on the container of seed treated with *NipsIt SUITE Cereals OF Seed Protectant*:

- Regardless of the type of application (seed treatment, soil or foliar), do not apply more than a total of 6.4 oz (181.4 gram) clothianidin (active ingredient) per acre per cropping cycle.
- Store away from feeds and other foodstuffs.
- Excess treated seed may be used for ethanol production only if (1) by-products are not used for livestock feed and (2) no measurable residues of pesticide remain in ethanol by-products that are used in agronomic practice.
- Wear long sleeved shirt, long pants and chemical resistant gloves when handling treated seed.
- Dispose of all excess treated seed. Left over treated seed may be double-sown around the headland or buried away from water sources in accordance with local requirements. Do not contaminate water bodies when disposing of planting equipment washwaters.
- Treated seeds must be planted at a minimum depth of 0.5 inch.
- This compound is toxic to birds and mammals. Treated clothianidin seeds exposed on soil surface may be hazardous to birds and mammals. Cover or collect seeds spilled during loading.
- This compound is highly toxic to bees exposed directly (contact). Ensure that planting equipment is functioning properly in accordance with manufacturing recommendations to minimize seed coat abrasion during planting to reduce dust which can drift to blooming crops or weeds.
- Do not re-use bags from treated seed to handle food or feed products.
- Dispose of seed packaging in accordance with local requirements.
- The compound is toxic to birds and mammals. Treated clothianidin seeds exposed on soil surface may be hazardous to birds and mammals. Cover or collect seeds spilled during loading.
- After seeds have been planted, do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 24 hours. Exception: Once seeds are planted and covered by soil or other planting media, the Worker Protection Standard (WPS) allows workers to enter the treated area without restriction."
- Areas planted with treated seed may be replanted immediately with bulb vegetables, canola, cereal grains (except rice), cotton, fruiting vegetables (including cucurbits), leafy vegetables (including brassica vegetables), rapeseed, root and tuber vegetables and soybean. These areas may also be replanted after 30 days with dry beans, grasses, non-grass animal feeds and rice. These areas may also be replanted after 8 months with sugarcane. Do not plant any other crop in the treated area for at least one year after these treated seeds are planted.

#### PRODUCT INFORMATION

*NipsIt SUITE Cereals OF Seed Protectant* is a systemic fungicide plus insecticide product formulated for seed treatment use to provide protection against seed-borne and soil-borne diseases and seed protection against wireworm. The fungicide active ingredients in *NipsIt SUITE Cereals OF Seed Protectant* are metconazole, a broad-spectrum, systemic, triazole fungicide, and metalaxyl, an Oomycete-active, systemic acylalanine fungicide. The fungicide components of *NipsIt SUITE Cereals OF Seed Protectant* provide activity against *Pythium spp.*, *Rhizoctonia solani*, *Fusarium spp.*, and other Deuteromycete and Basidiomycete (smut and bunt) fungi. Clothianidin is a systemic insecticide in *NipsIt SUITE Cereals OF Seed Protectant* giving seed protection against wireworm.



## MODES OF ACTION

Metalaxyl fungicide contained in *NipsIt INSIDE* Cereals OF Seed Protectant is a member of the acylalanine chemical group (FRAC Code 4) and interrupts fungal nucleic acid synthesis. Metconazole belongs to the sterol biosynthesis inhibitor group of fungicides (FRAC Code 3). Clothianidin is a neonicotinoid insecticide (IRAC MoA Group 4A) acting as a nicotine acetylcholine receptor agonist/antagonist in insect metabolism.

## APPLICATION DIRECTIONS

Accurate application of *NipsIt SUITE* Cereals OF Seed Protectant to seed is required for control of pests. *NipsIt SUITE* Cereals OF Seed Protectant is ready to use and may be applied direct to seed as formulated. However, to enhance uniform seed coverage, dilution with water may be appropriate for some types of treaters and/or treating seed under dry and/or hot conditions. If so, mix *NipsIt SUITE* Cereals OF Seed Protectant and water thoroughly into slurry before treating seed. Recalibrate treating equipment to compensate for the addition of water. The amount of dilution water that is most suitable depends on the seed, treating equipment, and the temperature.

For preparation of product in a slurry mixture with water, use the following guideline:

<i>NipsIt SUITE</i> Cereals OF Seed Protectant Use Rate:	Amount of water to be added to product:	Total Slurry Volume to apply per cwt. seed:
5.0 fl.oz./cwt. seed	5.0 – 10 fl.oz.	10.0 – 15 fl.oz.
7.5 fl.oz./cwt. seed	7.5 fl.oz./cwt.	15 fl.oz./cwt.

Use standard slurry or mist-type seed treatment equipment.

The following tables provide use rates of *NipsIt SUITE* Cereals OF Seed Protectant by labeled crop, with disease and insect protection guidelines:

BARLEY			
Seed/Seedling Diseases	Insect Pests	<i>NipsIt SUITE</i> Cereals OF Seed Protectant Use Rates	
		fl oz/100 lbs seed	<sup>1</sup> active Ingredient (mg ai/seed)
Covered Smut Loose Smut Seed Decay Fungi Fusarium Seed Scab Pythium Seed Rot and Seedling Dieback Early Season Fusarium Seedling Dieback Early Season Rhizoctonia Root Rot Early Season Common Root Rot	Wireworm	5.0 -7.5	Clothianidin (0.00333 -0.005)  Metalaxyl (0.001 -0.0015)  Ipconazole (0.00049-0.00074)
Regardless of type of application (seed treatment, soil or foliar ), do not apply more than a total of 6.4 oz (181.4 gram) active ingredient clothianidin per acre per cropping cycle.			

<sup>1</sup>mg active ingredient per seed is based on 13,605 seeds per pound



OATS			
Seed/Seedling Diseases	Insect Pests	NipsIt SUITE Cereals OF Seed Protectant Use Rates	
		fl oz/100 lbs seed	<sup>1</sup> active Ingredient (mg ai/seed )
Loose Smut Seed Decay Fungi Fusarium Seed Scab Pythium Seed Rot and Seedling Dieback Early Season Fusarium Seedling Dieback Early Season Rhizoctonia Root Rot Early Season Common Root Rot	Wireworm	5.0 -7.5	Clothianidin (0.00238 -0.00357)  Metalaxyl (0.00072 -0.00107)  Metconazole (0.00035-0.00053)
Regardless of type of application (seed treatment, soil or foliar ), do not apply more than a total of 6.4 oz (181.4 gram) active ingredient clothianidin per acre per cropping cycle			

<sup>1</sup> mg active ingredient per seed is based on 19,047 seeds per pound



WHEAT			
Seed/Seedling Diseases	Insect Pests	NipsIt SUITE Cereals OF Seed Protectant Use Rates	
		fl oz/100 lbs seed	<sup>1</sup> active Ingredient (mg.ai/seed)
Common Bunt Flag Smut Loose Smut Seed Decay Fungi Fusarium Seed Scab Pythium Seed Rot and Seedling Dieback Early Season Fusarium Seedling Dieback Early Season Rhizoctonia Root Rot Early Season Common Root Rot	Wireworm	5.0 -7.5	Clothianidin (0.004 -0.006mg)  Metalaxyl (0.0012 -0.0018 mg)  Metconazole (0.00059-0.00089 mg)
Regardless of type of application (seed treatment, soil or foliar ), do not apply more than a total of 6.4 oz (181.4 gram) active ingredient clothianidin per acre per cropping cycle			

<sup>1</sup> mg active ingredient per seed is based on 11,338 seeds per pound



## STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage and disposal.

### PESTICIDE STORAGE

Store in a dry place away from excessive heat.

Do not store near food or feed.

Store in original container only.

To close package, replace and tighten cap to form an airtight seal.

### PESTICIDE DISPOSAL

To avoid wastes, use all material in this container by application according to label directions. If wastes cannot be avoided, offer remaining product to a waste facility or pesticide disposal program (often such programs are run by state or local governments or by industry).

### CONTAINER HANDLING

*[Use the following statement for containers equal to or less than 5 gallons]*

Nonrefillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container 1/4 full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Offer for recycling, if available; otherwise dispose of in a sanitary landfill or incinerator.

*[Use the following statement for containers greater than 5 gallons]*

Nonrefillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container 1/4 full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times. Offer for recycling, if available; otherwise dispose of in a sanitary landfill or incinerator.

*[Use the following statement for all formulation types/all refillable container types]*

Refillable container. Refill this container with pesticide only. Do not reuse this container for any other purpose. Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. To clean the container before final disposal, empty the remaining contents from this container into application equipment or mix tank. Fill the container about 10 percent full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this rinsing procedure two more times. Offer for recycling, if available; otherwise dispose of in a sanitary landfill or incineration.

### RECYCLING

Once cleaned, some agricultural plastic pesticide containers can be taken to a container collection site or picked up for recycling. To find the nearest site, contact your chemical dealer or manufacturer, or contact the Ag Container Recycling Council (ACRC) at 877-952-2272 (toll free) or [www.acrecycle.org](http://www.acrecycle.org).



*NipsIt* is a trademark of Valent U.S.A. Corporation

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Manufactured For:

**Valent U.S.A. Corporation**

P. O. Box 8025

Walnut Creek CA 94596-8025

Made in U.S.A.

EPA Reg. No. 59639-183

EPA Est. No.

059639-00183.20111220 Rev 1 NipsItSuiteCereal  
20111219.20111214.20110609





RE: epa 59639-183  
Shen, Sue to: Marianne Lewis

12/20/2011 05:36 PM

1 attachment



0059639-00183 20111220 Rev 1 NipsIt SUITE OF Cereals new prod label.pdf

Marianne:

Please see the final revision per your request. Thanks

Sue-Chi Shen  
Regulatory Project Manager

Valent U.S.A. Corporation

2301 Ohio Drive, Suite 137 Plano, TX 75093  
Direct (972) 244-6543 Mobile (214) 784-5536 Confidential Fax (925)  
817-5910

-----Original Message-----

From: Marianne Lewis [mailto:Lewis.Marianne@epamail.epa.gov]  
Sent: Tuesday, December 20, 2011 2:19 PM  
To: Shen, Sue  
Subject: RE: epa 59639-183

I am working at a disadvantage here - haven't ever seen the hopper/planter boxes. So your product is not to be used in a planter or hopper box? Then how about putting the restriction "Do not use planter box or hopper box when applying product to seeds." on the label?

From: "Shen, Sue" <Sue.Shen@valent.com>  
To: Marianne Lewis/DC/USEPA/US@EPA  
Date: 12/20/2011 02:46 PM  
Subject: RE: epa 59639-183

Lewis: Sorry to get back to you late since I am in CA attending the meeting.

- 1) Remove Triticale
- 2) On page 5 of the label, move the 2nd paragraph under "Precautions and Restrictions" ("As stated by regulations specified.... or feed for animals.") to the seed bag tag

\* The statement is designed for the applicator who knows there is no need to add additional dye. This does not pertain to the growers who plant the treated seeds. What is critical for the growers is "Do not use treated seed for feed, food or oil processing." which is



already on the seed tag.

3) On page 5 of the label, revise the sub header "Seed Bag Tag" to read "Seed Bag Tag (all text that follows shall appear on seed bag tag)" or Something to that effect - so that the farmers get all of the Information that they need to safely use this product

L

All of the applicators are well trained to follow the requirements under seed tag section.

Traditionally, registrant (such as Valent) provides the seed tags or templates to the applicators.

4) On page 6 of the label, add the following bullet to the seed bag tag: "Do not feed clippings, crop waste or vines to livestock. Do not graze Treated areas."

Tolerances are set for all of RACs , no grazing restriction are required

5) On page 11 of the label, fix the "Pesticide Disposal" statement - "If Wastes..... Pesticide disposal program (...)" (Missing words are Underlined) - it appears that the wrap around part of the program is Overshooting the box.

Fixed. Sorry for the mistake.

6)

"Do not apply this product in hopper box or planter box at planting Time."

Just to make sure this product can not be dumped in the planter box and mixed with sees with the stick at planting time. It only can be applied utilizing mechanical, slurry, or mist-type seed treating equipment.

Thanks

Sue-Chi Shen  
Regulatory Project Manager

Valent U.S.A. Corporation

2301 Ohio Drive, Suite 137 Plano, TX 75093  
Direct (972) 244-6543 Mobile (214) 784-5536 Confidential Fax (925) 817-5910

-----Original Message-----

From: Marianne Lewis [mailto:Lewis.Marianne@epamail.epa.gov]  
Sent: Tuesday, December 20, 2011 7:22 AM  
To: Shen, Sue  
Subject: epa 59639-183

Sue,

A couple of things:

1) Was looking in the eCFR double checking the tolerances for metconazole and there is no tolerance listed for Triticale under metconazole ...so this use site will have to be deleted from the label for this action.



2) On page 5 of the label, move the 2nd paragraph under "Precautions and Restrictions" ("As stated by regulations specified.... or feed for animals.") to the seed bag tag.

3) On page 5 of the label, revise the subheader "Seed Bag Tag" to read "Seed Bag Tag (all text that follows shall appear on seed bag tag)" or something to that effect - so that the farmers get all of the information that they need to safely use this product.

4) On page 6 of the label, add the following bullet to the seed bag tag: "Do not feed clippings, crop waste or vines to livestock. Do not graze treated areas."

5) On page 11 of the label, fix the "Pesticide Disposal" statement - "If wastes..... pesticide disposal program (...)" (missing words are underlined) - it appears that the wrap around part of the program is overshooting the box.

One more thing - Venus and I were looking at this label - on page 5 under "Precautions and Restrictions" in the first paragraph the sentence "Do not apply this product in hopper box or planter box at planting time." has us a bit confused. So, are you telling the farmer that this is to be applied to the seed and then stored (are you going to supply the farmer with the seed bag tag to put on the stored grain) OR are you telling the farmer to apply it to the grain, let it dry thoroughly and then plant it? OR should this be applied on farm at all? Can you elaborate on what Valent wants to explain here - and include more specific directions than just this sentence.

Thanks much - will really like to finish this today if at all possible.

Marianne

[attachment "0059639-00183 20111220\_NipsIt SUITE OF Cereals new prod label.pdf" deleted by Marianne Lewis/DC/USEPA/US]







5-2  
12/9/11

Dear Ms. Shen:

In order to move forward with the label amendment for your product, EPA Reg. No. 59639-RIG, please make the following revisions to your label:

- ✓ 1. On page 1 of the label, revise "...systemic seed and seedling protection against early season cereal..." to read "... systemic seed and seedling protection against **listed** early season cereal..." (change indicated in **bold**)
- ✓ 2. On page 1 of the label, revise "EPA Reg. No. 59639-XXX" to read "EPA Reg. No. 59639-**183**" (change indicated in **bold**)
- ✓ 3. On page 2 of the label, for clarity and consistency increase the font size of the header "Precautionary Statements" so that it matches the "Directions for Use" font size and center the header in the middle of the column.
- ✓ 4. On page 2 of the label, for clarity and consistency decrease the font size of "Personal Protective Equipment (PPE)" – this is a section under the subheader "Hazards to Humans and Domestic Animals" – they are not equivalent.
- ✓ 5. On page 2 of the label, for consistency and clarity revise the subheader "Applicators and other handlers must wear" to read "**Mixers, loaders**, applicators and other handlers must wear:" (change indicated in **bold**)
- ✓ 6. On page 2 of the label, for clarity and consistency under "Personal Protective Equipment (PPE)" revise "If there are no such instructions for washable, use detergent..." to read "If **no such instructions for washables exist**, use detergent..." (change indicated in **bold**)
7. On page 2 of the label, for consistency and clarity under "Environmental Hazards" replace the existing statements with the following:

✓ "This product is toxic to aquatic invertebrates. Do not apply directly to water or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment wash water or rinsate. Do not apply where runoff is likely to occur. Drift and runoff may be hazardous to aquatic organisms in water adjacent to treated areas. Apply this product only as specified on label.

Treated seed exposed on soil surface maybe hazardous to birds. Cover or collect spilled seeds.

Metalaxyl has properties and characteristics associated with chemicals detected in ground water. This chemical may leach into ground water if used in areas where soils are permeable, particularly where the water table is shallow. Therefore contain any



product spills or equipment leaks and dispose of wastes according to the disposal instructions on this label.

- ✓ 8. On page 5 of the label, for consistency and clarity the Agency encourages the use of a "Resistance Management" box – similar to the one used for EPA Reg. No. 59639-176.
- ✓ 9. On page 5 of the label, for consistency and clarity under "Precautions and Restrictions" revise "... in accordance with use instructions on this label..." to read "... in accordance with **specifications** on this label..." (change indicated in **bold**)
- ✓ 10. On page 5 of the label, for consistency and clarity under "Precautions and Restrictions" revise "...dye or colorant to visually distinguish seed is treated with a ..." to read "...dye or colorant to visually distinguish seed **that** is treated with a ..." (change indicated in **bold**)
11. On page 5 of the label, under "Precautions and Restrictions" it states that the product is already colored as per 40 CFR 153.155 ("This product contains such dye or colorant.") Just double checking – does the product does contain the prescribed coloring?
12. On page 5 of the label, for consistency and clarity under "Seed Bag Tag" revise the second bullet to read as follows:
  - "Do not use treated seed for feed, food or oil processing. **Excess treated seed may be used for ethanol production only if (1) by-products are not used for livestock feed and (2) no measurable residues of pesticide remain in ethanol by-products that are used in agronomic practice.**" (changed indicated in **bold**)
- ✓ 13. On page 5 of the label, for consistency and clarity under "Seed Bag Tag – In addition, the US EPA" revise the third bullet to read as follows:
  - "Wear long sleeved shirt, long pants, and chemical resistant gloves when handling treated seed."
- ✓ 14. On page 5 of the label, for consistency and clarity under "Seed Bag Tag – In addition, the US EPA" revise the sixth bullet to read as follows:
  - "The compound is toxic to birds and mammals. Treated clothianidin seeds exposed on soil surface may be hazardous to birds and mammals. Cover or collect seeds spilled during loading."
- ✓ 15. On page 5 of the label, for consistency and clarity under "Seed Bag Tag – In addition, the US EPA" after the fourth bullet ("Dispose of all treated...") add the following bullets:
  - "Treated seeds must be planted at a minimum depth of 1 inch."

changed to 0.5 inch



- ✓ - "This compound is highly toxic to bees exposed directly (contact). Ensure that planting equipment is functioning properly in accordance with manufacturing recommendations to minimize seed coat abrasion during planting to reduce dust which can drift to blooming crops or weeds."
- "Do not re-use bags from treated seed to handle food or feed products."

✓ 16. On page 6 of the label, the bullet at the top of the page, "Areas planted with treated seed may be replanted...", states the same information that the table directly below, "Rotational Crop Plant-Back Intervals", to save space on the label and to avoid redundancy the Agency recommends that you pick one or the other to appear on the label.

✓ 17. On page 6 of the label, for clarity and consistency revise the subheader "Use Information" to read "**Product Information**." (change indicated in **bold**)

✓ 18. On page 7 of the label, the first paragraph under the subheader "Application Directions" is confusing – please rewrite more clearly.

✓ 19. On page 7 of the label, for clarity and consistency in the chart revise the subheader "Disease and Insect Protection for" to read "Disease and Insect **Pests**" (change indicated in **bold**)

✓ 20. On page 7 of the label, for clarity and consistency in the chart please add a column under "Use Rates" for "mg active ingredient per seed." See EPA Reg. No. 59639-176 for example. Also add a box at the bottom where the restrictions are clearly laid out – like 59639-176.

— 21. On page 8 of the label, for consistency and clarity in the "Storage and Disposal" box revise the subheader "Container Handling" to read "**Pesticide Container Disposal**" (change indicated in **bold**)

✓ 22. On page 8 of the label, for consistency and clarity and as per PR Notice 2007-4 under "Storage and Disposal – greater than 5 gallons" revise "...ensuring at least one complete revolution, for 30 seconds. Turn the container..." to read "...ensuring at least one complete revolution, for 30 seconds. **Stand the container on its end and tip it back and forth several times.** Turn the container ..." (changes indicated in **bold**)

✓ 23. On page 8 of the label, should you wish to add/retain the company's website on your label, then please be aware that the language presented in the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to the false and misleading provisions of 40 CFR 156.10(a)(5). Therefore should the Agency find or if it is brought to our attention that a website contains claims substantially differing from the EPA approved section 3 registration, the website will be referred to the EPA's Office of Enforcement and Compliance Assurance.



Please submit these label changes back to me via email ([lewis.marianne@epa.gov](mailto:lewis.marianne@epa.gov)) as soon as possible so that I can proceed with this action and stamp off on a clean label.

If you have any questions please call or email.

Thanks,

Marianne Lewis  
Biologist  
IRB/RD  
703 308-8043





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS  
REGISTRATION DIVISION (7505P)

December 6, 2011

**MEMORANDUM:** Acute Toxicity DER for 59639-RIG

Subject: Name of Pesticide Product: NIPSIT™ SUITE CEREALS OF SEED PROTECTANT  
EPA Reg. No. /File Symbol: 59639-RIG  
DP Barcode: DP 391343  
Decision No.: 450326  
Action Code: R310  
PC Code: 044309 (Clothianidin: 2.93%)  
113501 (Metalaxyl: 0.88%)  
125619 (Metconazole: 0.44%)

From: Byron T. Backus, Ph.D., Toxicologist  
Technical Review Branch  
Registration Division (7505P)

*Byron T. Backus*  
*Dec. 6 2011*  
*B. Backus*

To: Marianne Lewis/Venus Eagle RM 01  
Insecticide-Rodenticide Branch  
Registration Division (7505P)

Registrant: VALENT U.S.A. CORPORATION

**FORMULATION FROM LABEL:**

<u>Active Ingredient(s):</u>	<u>by wt.</u>
044309 Clothianidin	2.93%
113501 Metalaxyl	0.88%
125619 Metconazole	0.44%
<u>Other Ingredient(s):</u>	<u>95.75%</u>
TOTAL	100.00%

"One gallon of Nipsit SUITE Cereals OF Seed Protectant contains 0.256 lbs clothianidin, 0.077 lbs metalaxyl, and 0.038 lbs metconazole."



**Action Requested:** The Risk Manager requests a review of six acute toxicity studies (MRIDs 48505203-48505208). The material received also includes a proposed label (no proposed signal word), a basic CSF dated June 15, 2011, and a cover letter dated June 9, 2011.

GLP: All six of the studies were conducted in accordance with GLP.

All six of the acute toxicity studies have been classified as acceptable. These studies satisfy the acute toxicity data requirements for the registration of EPA File Symbol 59639-RIG.

Deficiencies: There were no deficiencies.

**Label Review:** The following is the precautionary and first aid labeling for this product, as obtained from the Label Review System:

**PRODUCT ID #:** 059639-00183

**PRODUCT NAME:** NIPSIT™ SUITE CEREALS OF SEED PROTECTANT

**PRECAUTIONARY STATEMENTS**

**SIGNAL WORD:** CAUTION (OPTIONAL)

**Hazards to Humans and Domestic Animals:**

Wear: Long-sleeved shirt and long pants, Socks, and Shoes.

**First Aid: (First aid statements are optional for this product)**



The following table is the Acute Toxicity Data Evaluation Record for the six studies submitted for the proposed product, EPA File Symbol 59639-RIG.

<b>1. DP BARCODE:</b> DP391343				
<b>2. PC CODES:</b> 044309 (Clothianidin: 2.93%); 113501 (Metalaxyl: 0.88%); 125619 (Metconazole: 0.44%)				
<b>3. CURRENT DATE:</b> December 6, 2011				
<b>4. TEST MATERIAL:</b> NipsIt™ SUITE Cereals OF Seed Protectant, Lot #: VT11A-3FS-1; a red opaque liquid, pH 6-8, containing 3.04% Clothianidin; 0.908% Metalaxyl; and 0.445% Metconazole				
Study/Species/Lab Study # / Date	MRID	Results	Tox. Cat.	Core Grade
Acute oral toxicity/rat Eurofins Product Safety Labs 31844 /May 24, 2011	48505203	LD <sub>50</sub> Females > 5000 mg/kg bw. 3 females dosed at 5000 mg/kg; all survived. All were hypoactive and had hunched posture and/or reduced fecal volume following administration. All recovered by Day 2.	IV	A
Acute dermal toxicity/rat Eurofins Product Safety Labs 31845 /May 24, 2011	48505204	No mortality; LD <sub>50</sub> Males > 5000 mg/kg bw LD <sub>50</sub> Females > 5000 mg/kg bw LD <sub>50</sub> Combined > 5000 mg/kg bw Erythema at dose site in all animals with clearing by day 5	IV	A
Acute inhalation toxicity/rat Eurofins Product Safety Labs 31846 /May 23, 2011	48505205	Nose-only inhalation LC <sub>50</sub> Males, Females, Combined > 2.06 mg/L with no mortality or signs of toxicity. MMAD = 2.99 µm; GSD = 2.15.	IV	A
Primary eye irritation/rabbit Eurofins Product Safety Labs 31847 /May 23, 2011	48505206	No positive irritation effects. At 1 hour all 3 eyes showed grade 1 redness and grade 1-2 discharge; all other scores zero. All scores zero at 24, 48 & 72 hours. MMTS = 5.3 (at 1 hr).	IV	A
Primary dermal irritation/rabbit Eurofins Product Safety Labs 31848 /May 24, 2011	48505207	The Primary Irritation Index (PII) is 2.0, and the mean irritation score at 72 hours = 0.67. All sites scored zero on day 7.	IV	A
Dermal sensitization/Guinea pig Eurofins Product Safety Labs 31849 /May 24, 2011	48505208	Buehler method. Not a sensitizer	-	A

Core Grade Key: A = Acceptable, S = Supplementary, U = Unacceptable, W = Waived



2 Beans  
**DATA PACKAGE BEAN SHEET**

Date: 13-Jul-2011

Page 1 of 3

Decision #: 450326

DP #: (391733)

PRIA

Parent DP #:

Submission #: 899459

E-Sub #:

FEE

\*\*\* Registration Information \*\*\*

**Registration:** 59639-RIG - NIPSIT SUITE CEREALS OF SEED PROTECTANT

Company: 59639 - VALENT U.S.A. CORPORATION

Risk Manager: RM 01 - Venus Eagle - (703) 308-8045 Room# PY1 S-7913

Risk Manager Reviewer: Marianne Lewis MLEWIS03

Sent Date: \_\_\_\_\_

Calculated Due Date: 01-Jan-2012

Edited Due Date: \_\_\_\_\_

Type of Registration: Product Registration - Section 3

Action Desc: (R310) NEW PRODUCT;NON-FAST TRACK (INCLUDES REVIEWS OF PRODUCT CHEMIST

Ingredients: See page 3

*R310  
#29160*

\*\*\* Data Package Information \*\*\*

Expedite: ☐ Yes ☒ No

Date Sent: 13-Jul-2011

Due Back: \_\_\_\_\_

DP Ingredient: See page 3

DP Title: revised prod chem group A 59639-RIG

CSF Included: ☐ Yes ☒ No

Label Included: ☐ Yes ☒ No

Parent DP #: \_\_\_\_\_

Assigned To

Date In

Date Out

Organization: RD / TRB

Last Possible Science Due Date: 02-Dec-2011

Team Name: CHEM

Science Due Date: \_\_\_\_\_

Reviewer Name: Suyann Mathur 12/01/11

12/05/11

Sub Data Package Due Date: \_\_\_\_\_

Contractor Name: \_\_\_\_\_

*New gr. A Report*

\*\*\* Studies Sent for Review \*\*\*

Printed on Page 2

\*\*\* Additional Data Package for this Decision \*\*\*

Can be printed on its own page

\*\*\* Data Package Instructions \*\*\*

Please review this resubmission of group A pc data. Registrant informed by Aswathy McFadden that there was an error on the upper limits of one of the inerts on the csf - corrected csf sent to Ms McFadden on 6/16/11. This revised report now reflects the changes in the csf and replaces MRID # 485052-01. Included is the hard copy of MRID # 485258-01 and a copy of the letter from Valent. Please close out the previous bean and review the pc now under this bean #. MRID # 485052-02 (group B) still applies. Let me know if you need anything else.  
Marianne 308-8043

*PREVIOUS DP # 391335  
WHICH WAS SENT 6/30/11  
LOGGED INTO TRB 7/7/11*



# DATA PACKAGE BEAN SHEET

Date: 30-Jun-2011

Page 1 of 3

Decision #: 450326

DP #: (391335)

PRIA

Parent DP #:

Submission #: 897569

**FEE**

## \*\*\* Registration Information \*\*\*

Registration: 59639-RIG - NIPSIT SUITE CEREALS OF SEED PROTECTANT

Company: 59639 - VALENT U.S.A. CORPORATION

Risk Manager: RM 01 - Venus Eagle - (703) 308-8045 Room# PY1 S-7228

Risk Manager Reviewer: Marianne Lewis MLEWIS03

Sent Date:

Calculated Due Date: 01-Jan-2012

Edited Due Date:

Type of Registration: Product Registration - Section 3

Action Desc: (R310) NEW PRODUCT;NON-FAST TRACK (INCLUDES REVIEWS OF PRODUCT CHEMIST

Ingredients: See page 3

R310  
#29113

## \*\*\* Data Package Information \*\*\*

Expedite: ☐ Yes ☒ No

Date Sent: 30-Jun-2011

Due Back:

DP Ingredient: See page 3

DP Title: product chemistry for 59639-RIG contains 3 al's

CSF Included: ☒ Yes ☐ No

Label Included: ☒ Yes ☐ No

Parent DP #:

Assigned To

Date In

Date Out

Organization: RD / TRB

Last Possible Science Due Date: 02-Dec-2011

Team Name: CHEM

Science Due Date:

Reviewer Name:

Shyann Mateo

12/1/11

12/05/11

Sub Data Package Due Date:

Contractor Name:

## \*\*\* Studies Sent for Review \*\*\*

Printed on Page 2

## \*\*\* Additional Data Package for this Decision \*\*\*

No Additional Data Packages

## \*\*\* Data Package Instructions \*\*\*

Please review the product chemistry data submitted for this new product, EPA Reg. No. 59639-RIG. The MRID's are 485052-01 (group A) and 485052-02 (group B). The inerts have been cleared for food use seed treatment only. Also included in the package is the basic csf, the 2 alternates and the label. Please let me know if you have any questions. Thanks, Marianne 308-8043

plus the registrant's MSDs for the product





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

FEE

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION  
OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

DP BARCODE No.: 391733, 391335; FILE SYMBOL No.: 59639-RIG; PRODUCT NAME: NIPSIT Suite  
Cereals of Seed Treatment; DECISION No.: 450326; PC Code(s): 044309, 113501, 125619; ACTION  
CODE: R310; FOOD Use: Yes

DATE OUT: December 5, 2011

SUBJECT: End Use Product Chemistry Review  
Product Name: NIPSIT Suite Cereals of Seed Treatment

FROM: Shyam Mathur  
Product Chemistry Team Leader  
Technical Review Branch/RD (7505P)

*SB Mathur*  
*12/5/11*  
*Tom*

TO: Marianne Lewis / Venus Eagle, RM 01  
Insecticide-Rodenticide Branch / RD (7505P)

Company Name: Valent USA Corporation  
Formulation Type: Ready-to-Use Seed Protectant Formulation

INTRODUCTION:

The registrant has submitted an application for the new end use product "NIPSIT Suite Cereals of Seed Treatment" containing three registered active ingredients. In support of the registration application, the registrant has originally submitted 830 series group A product chemistry data with MRID No. 485052-01 which was replaced by amended report submitted on June 30, 2011 with MRID No. 485258-01. The 830 series group B data was submitted with MRID No. 485052-02. The registrant has submitted a CSF for basic formulation (dated 06-15-11), an alternate CSF#1 (dated 06-16-11) and alternate CSF #2 (dated 06-17-11) along with the product label. TRB has been asked to determine the acceptability of product chemistry data submitted to support the basic & alternate CSF's.

SUMMARY OF FINDINGS:

1. Name of Active Ingredient(s): Clothianidin (2.93%), Metalaxyl (0.88%), Metconazole (0.44%)

2. Has the registrant claimed substantial similarity to a registered product?

☐ Yes; ☒ No; ☐ NA; if yes give the registration number of the cited product.

EPA Reg. No: NA

3. All of the source materials of the active ingredient are derived from registered sources- ☒ Yes ☐ No

4. All inert ingredients have been screened by IIAB and found to be approved for the proposed labeled Uses?

☐ Yes; ☒ No;

Note: One of the inert ingredient is not approved for the food use.

← THIS WAS APPROVED  
FOR SEED USE ONLY

-ML  
86/2/11



DP BARCODE No.: 391733, 391335; FILE SYMBOL No.: 59639-RIG; PRODUCT NAME: NIPSIT Suite  
Cereals of Seed treatment; DECISION No.: 450326; PC Code(s): 044309, 113501, 125619; ACTION CODE:  
R310; FOOD Use: Yes

5. Confidential Statement of Formula(s):

☒ Basic - Dated: 06/15/11; Re-submitted - Dated: NA

☒ Alternate #1 - Dated: 06/16/11, Alternate #2 - Dated: 06/17/11; Re-submitted - Dated: NA

Alternate CSF(s) complies with 40CFR§152.43: ☒ Yes; ☐ No; ☒ NA

6. Product label

- a. Ingredient statement: Nominal concentration of AI listed on CSF(s) concurs with product label (PR Notice 91-2).

☒ Yes; ☐ No; if not, explain below:

Is the sub statement in compliance with PR Notice 97-6 (inert ingredient vs other ingredient)

☒ Yes; ☐ No; if not, explain below:

Metallic equivalent: ☐ Yes ☒ NA

Soluble arsenic: ☐ Yes ☒ NA

Isomeric ratios: ☐ Yes ☒ NA

Acid Equivalent: ☐ Yes ☒ NA acid equivalent = NA

- b. Health related sub statements: Product contains?

Petroleum distillate at > 10%: ☐ Yes ☒ No ☐ NA

Methanol at > 4%: ☐ Yes ☒ No ☐ NA

Sodium nitrate/Sodium nitrite: ☐ Yes ☒ No ☐ NA

- c. Physical chemical hazard statement: Product label requires a statement per 40 CFR §156.78 for: flammability, explosive potential or electric insulator breakdown?

☐ Yes; ☒ No

Is the sub statement in compliance with PR Notice 98-6 (Total Release Fogger)?

☒ Yes; ☐ No; ☐ NA; if not, explain below

- d. Label requires an additional Storage and Disposal statement:

☐ Yes; ☒ No; if yes explain below:



DP BARCODE No.: 391733, 391335; FILE SYMBOL No.: 59639-RIG; PRODUCT NAME: NIPSIT Suite  
Cereals of Seed treatment; DECISION No.: 450326; PC Code(s): 044309, 113501, 125619; ACTION CODE:  
R310; FOOD Use: Yes

7. Group A: Product Chemistry Data

TRB's determination of the acceptability for the proposed product is listed in the tables below.

Guideline No.	Study Title		Data submitted		TRB's Assessment of Data	MRID Nos.
			Yes	No		
830.1550	Product Identity & Composition		X		A	485258-01
830.1600	Description of materials used to produce the product		X		A	485258-01
830.1650	Description of formulation process		X		A	485258-01
830.1670	Discussion on the formation of impurities		X		A	485258-01
830.1700	Preliminary analysis				NA	
830.1750	Certified limits (158.350)	Standard certified limits	X		A	
		Proposed Limits				
		Justification for wider limits				
830.1800	Enforcement analytical method		X		A	485258-01

A = Acceptance, N = Not Acceptable, G = Data Gap, W = Waiver Request, I = In Progress, NA = Not Applicable; U = Upgradeable.



**DP BARCODE No.:** 391733, 391335; **FILE SYMBOL No.:** 59639-RIG; **PRODUCT NAME:** NIPSIT Suite  
**Cereals of Seed treatment;** **DECISION No.:** 450326; **PC Code(s):** 044309, 113501, 125619; **ACTION CODE:**  
**R310;** **FOOD Use:** Yes

8. Group B:

Guideline No.	Study Title	Value or Qualitative Description	TRB's Assessment of Data	MRID Nos.
830.6303	Physical State	Liquid	A	485052-02
830.6315	Flammability	NA		
830.6316	Explodability	NA		
830.7000	pH	5.94 @ 25.0°C	A	485052-02
830.7300	Density (units)	1.05 g/mL @ 20.0°C	A	485052-02

A = Acceptance, N = Not Acceptable, G = Data Gap, W = Waiver request, NA = Not applicable, I = In progress; U = Upgradeable.



**DP BARCODE No.:** 391733, 391335; **FILE SYMBOL No.:** 59639-RIG; **PRODUCT NAME:** NIPSIT Suite  
**Cereals of Seed treatment:** **DECISION No.:** 450326; **PC Code(s):** 044309, 113501, 125619; **ACTION CODE:**  
**R310;** **FOOD Use:** Yes

#### **CONCLUSIONS:**

The TRB has reviewed the product chemistry data submitted for the proposed end-use product and has concluded that:

1. The proposed CSF for basic formulation (dated 06-15-11), CSF alt #1 (06-16-11) and CSF alt #2 (06-17-11) are acceptable.
2. The data submitted corresponding to guidelines 830.1600 (description of materials used to produce the product), 830.1650 (description of formulation process), 830.1670 (discussion on the formation of impurity), 830.1750 (certified limits) and 830.1800 (enforcement analytical method) are acceptable.
3. The product chemistry data submitted corresponding to guidelines 830.6302 (color), 830.6303 (physical state), 830.6304 (odor), 830.6314 (oxidizing/reduction), 830.6315 (flammability), 830.6316 (explosibility), 830.7000 (pH), 830.7100 (viscosity) and 830.7300 (density) are acceptable.
4. The registrant has stated that the studies for one year storage stability (830.6317) and corrosion characteristics (830.6320) for the proposed product are in progress and the results will be submitted to Agency for evaluation. It is recommended that the observations should be made at 0, 3, 6, 9 and 12 month intervals.





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

July 6, 2011

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

DANIEL P. FAY  
VALENT U.S.A. CORPORATION  
1600 RIVIERA AVENUE, SUITE 200  
WALNUT CREEK, CA 94596

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 01-JUL-11. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.



**Receipt for Section 3**

S:

Resubmission: ☐ Yes ☒ No

Regulatory Type:

Fee For Service: ☐ Yes ☒ No

Application Type:

Billable: ☒ Yes ☐ No

Company:

Risk Manager:

Product #:  Product Name:

Override#:

Me Too Section3:  Me Too Product Name:

Application Date:  OPP Rec'd Date:

Front End Date:  Risk Manager Send Date:

FFS Due Date:  Negotiated Due Date:

OPP Target Date:

Fast Track: ☐ New Ingredient: ☐

Receipt Description:

One product chemistry study

Form A: ☐ Signature Date:  Form B: ☐ Signature Date:

New Ingredient Request Date:

New Ingredient Received Date:

Receipt Content

Study

View/Edit

Print Letter

Enter More Information

Tracking







## DATA TRANSMITTAL DOCUMENT

**ACTIVE INGREDIENT(S):** Clothianidin, Metalaxyl, Metconazole

**PRODUCT NAME(S):** NipsIt™ SUITE Cereals OF Seed Protectant

**EPA ID NUMBER(S):** 59639-RIG

**SUBMITTER:** Valent U.S.A. Corporation  
P. O. Box no. 8025  
Walnut Creek, CA 94596-8025

**TRANSMITTAL DATE:** June 30, 2011  
[Initial Submission Date June 09, 2011]

**REGULATORY ACTION SUPPORTED:** Submission of Revised Product Chemistry Group-A Report

Volume Number	Guideline Number	Study	MRID Number
1.	830.1550	Title: Product Product Identity and Composition of NipsIt™ SUITE Cereals OF Seed Protectant	<b>48525801</b>
	830.1600	Description of Materials Used to Produce the Product NipsIt™ SUITE Cereals OF Seed Protectant	
	830.1620	Description of Manufacturing Process for NipsIt™ SUITE Cereals OF Seed Protectant	
	830.1650	Description of Formulation Process for NipsIt™ SUITE Cereals OF Seed Protectant	
	830.1670	Discussion of Formation of Impurities for Process for NipsIt™ SUITE Cereals OF Seed Protectant	
	830.1700	Preliminary Analysis of Process for NipsIt™ SUITE Cereals OF Seed Protectant	
	830.1750	Certified Limits for Process for NipsIt™ SUITE Cereals OF Seed Protectant	
	830.1800	Analytical Method for Process for NipsIt™ SUITE Cereals OF Seed Protectant	
	830.1900	Submittal of Samples for Process for NipsIt™ SUITE Cereals OF Seed Protectant	

Author: Evelyn J. Taylor  
Lab ID no.: 2011-10304-001  
Study Completion Date: 21 June 2011  
Valent Accession no.: 201100153 A&B





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

June 17, 2011

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

DANIEL P. FAY  
VALENT U.S.A. CORPORATION  
1600 RIVIERA AVENUE, SUITE 200  
WALNUT CREEK, CA 94596

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 10-JUN-11. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.



# Receipt for Section 3

S: 897569

Resubmission: ☐ Yes ☒ No

Regulatory Type: Product Registration - Section 3

Fee For Service: ☒ Yes ☐ No

Application Type: New Registration

Billable: ☒ Yes ☐ No

Company: 58639 VALENT U.S.A. CORPORATION

V

Risk Manager: Registration Division, Risk Management Team 1

Product #: 59639-RIG

Product Name: NIPSLT SUITE CEREALS OF SEED PROTECTA

Override:

Me Too

Me Too

Section3:

Product Name:

Application Date: 09-Jun-2011

id

OPP Rec'd Date: 10-Jun-2011

id

Front End Date: 10-Jun-2011

id

Risk Manager Send Date:

id

FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Receipt Content

Study

CSF

View/Edit

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

A new end use product

New Ingredient

Request Date:

New Ingredient

Received Date:

Form A: ☐

Signature Date:

Form B: ☐

Signature Date:



## Memorandum

Date: 6 / 17 / 11

To: PMI, Regulatory Manager

From: Information Services Branch, ITRMD

Your receipt of this data submission is not an indication that MRIDs for the enclosed studies have been posted to OPPIN.

**We expect that it will be approximately 5 days from the above date before the study-level data is available in OPPIN.**

If you have any questions about this process, please contact Teresa Downs (305-5363).

This is a: ☒ fully accepted submission  
☐ partially accepted submission  
☐ rejected submission



# Fee for Service

{897569k~

This package includes the following

- ☒ New Registration
- ☐ Amendment

☒ Studies? ☐ Fee Waiver?  
☐ volpay % Reduction: \_\_\_\_

for Division

- ☐ AD
- ☐ BPPD
- ☒ RD

Risk Mgr. 1

Receipt No.

S- 897569

EPA File Symbol/Reg. No.

59639-RIG

Pin-Punch Date:

6/10/2011

☐ This item is NOT subject to FFS action.

## Action Code:

Requested: E310

Granted: E310

Amount Due: \$ 4807

*Inerts approved. AB 06/17/11*

☒ Inert Cleared for Intended Use



Uncleared Inert in Product

Reviewer: D. Hill

Date: 6/13/11

Remarks:



Valent U.S.A. Corporation  
1800 Eureka Avenue, Suite 200  
Walpole, MA 01981-1000



16 June 2011

U.S. Environmental Protection Agency  
Document Processing Desk  
Office of Pesticide Programs (7505P)  
Room S-4900, One Potomac Yard  
2777 South Crystal Drive  
Arlington, VA 22202-4501

Attention: ASWATHY BALAN, MACFADDEN EPA CONTRACTOR

Subject: EPA Email 06/15/11 NipsIt™ Suite Cereals OF Seed Protectant Submission 06/09/11

Dear Sirs and/ or Dames:

Per your request, please find enclosed:

1. Product Chemistry Group B report/ Transmittal Doc no. 2 [3-Copies].
2. Data Matrix for End-Use Product [1-EPA & 1-Public].

Also enclosed:

3. Data Transmittal Document 06/09/11.
4. EPA Email of 06/15/11.

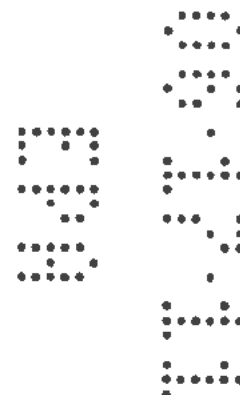
Thank you.

Respectfully yours,

Lisa V. Cortez  
Regulatory Analyst  
Registration and Regulatory Affairs  
Tel: 925-256-2740, Email: [lisa\\_cortez@valent.com](mailto:lisa_cortez@valent.com)

Enclosures: [ 7 ]

Copy: S.C Shen  
Valent Central Files







UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

June 13, 2011

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

OPP Decision Number: D-450326  
EPA File Symbol or Registration Number: 59639-RIG  
Product Name: NIPSLT SUITE CEREALS OF SEED PROTECTANT  
EPA Receipt Date: 10-Jun-2011  
EPA Company Number: 59639  
Company Name: VALENT U.S.A. CORPORATION

DANIEL P. FAY  
VALENT U.S.A. CORPORATION  
1600 RIVIERA AVENUE, SUITE 200  
WALNUT CREEK, CA 94596

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application and certification of payment. If you submitted data with this application, the results of the PRN-86-5 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R310

NEW PRODUCT;NON-FAST TRACK (INCLUDES REVIEWS OF PRODUCT  
CHEMISTRY;ACUTE TOXICITY;PUBLIC HEALTH PEST EFFICACY);

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee  
Ombudsman at (703) 308-9362.

Sincerely,

A handwritten signature in black ink, appearing to read "m. j. lee".

Front End Processing Staff  
Information Technology & Resources Management Division



# PRIA 2 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

3/23/09

21 Day Screen Start Date: 6-10-11

Experts In-Processing Signature: B. R.

Date 6-13-11

Fee Paid: Yes ☒

Division management contacted on issues No ☐ Yes ☐ Date \_\_\_\_\_

EPA Reg. Number: <u>59639-RIG</u>		EPA Receipt Date: <u>6-10-11</u>														
Items for Review			Yes	No	N/A*											
1	<b>Application Form</b> (EPA Form 8570-1)(link to form) signed & complete including package type		<input checked="" type="checkbox"/>													
2	<b>Confidential Statement of Formula</b> all boxes completed, form signed, and dated (EPA Form 8570-4) (Link to form) <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 5px;"> <tr> <td style="padding: 5px;">a) All inerts (link to <a href="http://www.epa.gov/oppr001/inerts/">http://www.epa.gov/oppr001/inerts/</a>), including fragrances, approved for the proposed uses (see Footnote A)</td> <td style="text-align: center; padding: 5px;">yes</td> <td style="text-align: center; padding: 5px;">no</td> </tr> <tr> <td></td> <td style="text-align: center; vertical-align: middle;"><input checked="" type="checkbox"/></td> <td style="text-align: center; vertical-align: middle;"><input type="checkbox"/></td> </tr> </table>	a) All inerts (link to <a href="http://www.epa.gov/oppr001/inerts/">http://www.epa.gov/oppr001/inerts/</a> ), including fragrances, approved for the proposed uses (see Footnote A)	yes	no		<input checked="" type="checkbox"/>	<input type="checkbox"/>		<input checked="" type="checkbox"/>							
a) All inerts (link to <a href="http://www.epa.gov/oppr001/inerts/">http://www.epa.gov/oppr001/inerts/</a> ), including fragrances, approved for the proposed uses (see Footnote A)	yes	no														
	<input checked="" type="checkbox"/>	<input type="checkbox"/>														
3	<b>Certification with Respect to Citation of Data</b> (EPA Form 8570-34) (Link to form) completed and signed (N/A if 100% repack)		<input checked="" type="checkbox"/>													
	Certificate and data matrix consistent		<input checked="" type="checkbox"/>													
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="text-align: center; padding: 5px;">yes</td> <td style="text-align: center; padding: 5px;">no</td> </tr> <tr> <td style="text-align: center; vertical-align: middle;"><input type="checkbox"/></td> <td style="text-align: center; vertical-align: middle;"><input type="checkbox"/></td> </tr> </table>	yes	no	<input type="checkbox"/>	<input type="checkbox"/>										
yes	no															
<input type="checkbox"/>	<input type="checkbox"/>															
	If applicable, is there a letter of Authorization for exclusive use only.															
4	<b>Formulator's Exemption Statement</b> (EPA Form 8570-27) (Link to form) completed and signed (N/A if source is unregistered or applicant owns the technical)		<input checked="" type="checkbox"/>													
5	<b>Data Matrix</b> (EPA Form 8570-35) (Link to form) both internal and external copies (PR 98-5) (Link to PR 98-5) completed and signed (N/A if 100% repack) <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 5px;"> <tr> <td style="padding: 5px;">a) Selective Method (Fee category experts use)</td> <td style="text-align: center; padding: 5px;">yes</td> <td style="text-align: center; padding: 5px;">no</td> </tr> <tr> <td></td> <td style="text-align: center; vertical-align: middle;"><input checked="" type="checkbox"/></td> <td style="text-align: center; vertical-align: middle;"><input type="checkbox"/></td> </tr> <tr> <td style="padding: 5px;">b) Cite-All (Fee category experts use)</td> <td style="text-align: center; padding: 5px;"></td> <td style="text-align: center; padding: 5px;"></td> </tr> <tr> <td style="padding: 5px;">c) Applicant owns all data (Fee category experts use)</td> <td style="text-align: center; padding: 5px;"></td> <td style="text-align: center; padding: 5px;"></td> </tr> </table>	a) Selective Method (Fee category experts use)	yes	no		<input checked="" type="checkbox"/>	<input type="checkbox"/>	b) Cite-All (Fee category experts use)			c) Applicant owns all data (Fee category experts use)				<input checked="" type="checkbox"/>	
a) Selective Method (Fee category experts use)	yes	no														
	<input checked="" type="checkbox"/>	<input type="checkbox"/>														
b) Cite-All (Fee category experts use)																
c) Applicant owns all data (Fee category experts use)																
6	<b>5 Copies of Label</b> (link to <a href="http://www.epa.gov/oppfead1/labeling/lrm/">http://www.epa.gov/oppfead1/labeling/lrm/</a> ) (Electronic labels on CD are encouraged and guidance is available)( link to <a href="http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm#labels">http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm#labels</a> )		<input checked="" type="checkbox"/>													



7	Is the data package consistent with PR Notice 86-5 (link to PRN 86-5)	X		
8	Notice of Filing (link to <a href="http://www.epa.gov/pesticides/regulating/tolerance_petitions.htm">http://www.epa.gov/pesticides/regulating/tolerance_petitions.htm</a> ) included with petitions (link to <a href="http://www.epa.gov/pesticides/regulating/tolerances.htm">http://www.epa.gov/pesticides/regulating/tolerances.htm</a> )			X
9	If applicable for conventional applications, reduced risk rationale (link to <a href="http://www.epa.gov/opprd001/workplan/reducedrisk.html">http://www.epa.gov/opprd001/workplan/reducedrisk.html</a> )			X
10	Required Data (link to <a href="http://www.epa.gov/pesticides/regulating/data_requirements.htm">http://www.epa.gov/pesticides/regulating/data_requirements.htm</a> ) and/or data waivers. See Footnote C.			
	a) List study (or studies) not included with application			



Comments:

- \* Study #2 was missing in the application package and the registrant send it via FedEx when contacted. Thus all the studies have passed the PRN-86-5 review.
- \* Data Matrix for <sup>one of</sup> the technicals was submitted and not for the end-use product. The registrant send it when contacted.
- \* Two inerts were having issues and they got fixed. See the inert status form in the CSF envelope for details. All the inerts are now approved for food use under 40 CFR 180.920, seed treatment only.

Jacket passed  
Studies passed

AB

MRID: 485052

\* N/A - Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses. If an unapproved inert is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses **even if a product is currently registered** by consulting the inert Web



site [link to <http://www.epa.gov/oppr001/inerts/lists.html>] and if the inert is not approved, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient.** Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at [inertsbranch@epa.gov](mailto:inertsbranch@epa.gov) and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the Chief of Microbial Pesticides Branch [Link to [http://www.epa.gov/oppbppd1/biopesticides/contacts\\_bppd.htm](http://www.epa.gov/oppbppd1/biopesticides/contacts_bppd.htm)].

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information [link to <http://www.epa.gov/oppr001/inerts/tips.pdf>] must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

#### **Unapproved Inerts Identified on CSFs**

##### **All applications except conventional new products and PIPs**

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;



3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

#### Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R311, R312 or R313), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)
3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

#### PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.



3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.





**RE: Submission to EPA: Product NipsIt Suite Cereals of Seed Protectant (Reg# 59639-RIG)**

**Shen, Sue** to: Aswathy Balan

06/17/2011 02:09 PM

Aswathy Balan :

Thanks so much for the prompt reply. Have a nice weekend.

Sue-Chi Shen  
Regulatory Project Manager

Valent U.S.A. Corporation

2301 Ohio Drive, Suite 137 Plano, TX 75093  
Direct (972) 244-6543 Mobile (214) 784-5536 Confidential Fax (925)  
817-5910

-----Original Message-----

From: Balan.Aswathy@epamail.epa.gov  
[mailto:Balan.Aswathy@epamail.epa.gov]  
Sent: Friday, June 17, 2011 1:02 PM  
To: Shen, Sue  
Subject: RE: Submission to EPA: Product NipsIt Suite Cereals of Seed  
Protectant (Reg# 59639-RIG)

Dear Ms. Shen,

I talked to Ms. Rock and she told me that she is approving that pigment under 40 CFR 180.920. I received the missing study and data matrix too. Now I guess all the issues have been corrected and I am forwarding your submission to the PM. Thanks for helping me in fixing the issues.

Aswathy Balan  
EPA Contractor  
2777 S. Crystal Drive, S-4810  
Arlington, VA 22202  
Ph: 703-347-8787

From: Aswathy Balan/DC/USEPA/US  
To: "Shen, Sue" <Sue.Shen@valent.com>  
Date: 06/17/2011 08:56 AM  
Subject: RE: Submission to EPA: Product NipsIt Suite Cereals of  
Seed  
Protectant (Reg# 59639-RIG)



Dear Ms. Shen,

I contacted you regarding this inert issue after consulting Ms. Sandra Rock in the Inerts Branch Team. I am sure she would be able to further assist you in this. Her contact info is 703-308-6164 / rock.sandra@epa.gov  
Let me know if you need any other help. Thanks.

Aswathy Balan  
EPA Contractor  
2777 S. Crystal Drive, S-4810  
Arlington, VA 22202  
Ph: 703-347-8787

From: "Shen, Sue" <Sue.Shen@valent.com>  
To: Aswathy Balan/DC/USEPA/US@EPA  
Date: 06/16/2011 03:54 PM  
Subject: RE: Submission to EPA: Product NipsIt Suite Cereals of Seed  
Protectant (Reg# 59639-RIG)

Aswathy Balan :

1) Pigment 48:2

Would you please check what the issue with [REDACTED] was?  
Is the issue relating to the status of [REDACTED] or something else in the composition?

40CFR 180.920 shows (with no CAS numbers)

[REDACTED]	For seed treatment use	Dye
only		

We assume that this should cover [REDACTED]

2) [REDACTED] Sorry for the oversight , we will send you a revised CSF to correct the upper limit .

Thanks

Sue-Chi Shen  
Regulatory Project Manager

Valent U.S.A. Corporation

2301 Ohio Drive, Suite 137 Plano, TX 75093  
Direct (972) 244-6543 Mobile (214) 784-5536 Confidential Fax (925)

\*Inert ingredient information may be entitled to confidential treatment\*



817-5910

-----Original Message-----

From: Balan.Aswathy@epamail.epa.gov [mailto:Balan.Aswathy@epamail.epa.gov]  
Sent: Thursday, June 16, 2011 9:52 AM  
To: Shen, Sue  
Subject: RE: Submission to EPA: Product NipsIt Suite Cereals of Seed Protectant (Reg# 59639-RIG)

Thanks for responding Ms. Shen, actually there were only two inert issues I had to convey to you. Sorry for the error.

Aswathy Balan  
EPA Contractor  
2777 S. Crystal Drive, S-4810  
Arlington, VA 22202  
Ph: 703-347-8787

From: "Shen, Sue" <Sue.Shen@valent.com>  
To: Aswathy Balan/DC/USEPA/US@EPA  
Cc: Sree Nair/DC/USEPA/US@EPA  
Date: 06/16/2011 10:47 AM  
Subject: RE: Submission to EPA: Product NipsIt Suite Cereals of Seed Protectant (Reg# 59639-RIG)

Aswathy Balan :

Thank for your email. The reports and data matrix will be sent by Friday.

Our formulation manager is working on the inert inquiry. Please verify to see if there are three (per your email) or two issues (per attachment).

Thanks

Sue-Chi Shen  
Regulatory Project Manager

Valent U.S.A. Corporation

2301 Ohio Drive, Suite 137 Plano, TX 75093  
Direct (972) 244-6543 Mobile (214) 784-5536 Confidential Fax (925) 817-5910

-----Original Message-----

From: Balan.Aswathy@epamail.epa.gov [mailto:Balan.Aswathy@epamail.epa.gov]  
Sent: Wednesday, June 15, 2011 10:08 AM  
To: Shen, Sue  
Cc: Nair.Sree@epamail.epa.gov  
Subject: Submission to EPA: Product NipsIt Suite Cereals of Seed



Protectant (Reg# 59639-RIG)

Dear Ms. Shen,

This email is regarding your Application for Registration of the product NipsIt Suite Cereals of Seed Protectant (Reg# 59639-RIG) . We have found the following issues with your application:

\* Three inert ingredients in the CSF have issues. See the attached inert status form to find the details.

(See attached file: 59639-RIG.doc)

\* The data matrix submitted is for Clothianidin Technical (59639-173) and not for the end use product. So please send a data matrix for the subject product.

\* Study #2 in the transmittal document, Physical and Chemical Properties, is missing in the application package. Send 3 copies of the study to the Document Processing Desk.

You can send the revised forms either by fax to 703-305-5060, Attn: Aswathy Balan or email to [balan.aswathy@epa.gov](mailto:balan.aswathy@epa.gov). If you have any questions, do not hesitate to call me back at 703-347-8787.

Thanks,

Aswathy Balan  
Macfadden, EPA Contractor  
2777 S. Crystal Drive, S-4810  
Arlington, VA 22202  
Phone: 703-347-8787



Script for Rejection Phone calls

Contact Name: Sue-Chi Shen  
Phone #: 214-784-5536  
Email: sshen@valent.com

First Call/Initials: AB

Date: 06/15/11

Time: 1:23 PM

Second Call/Initials:

Date:

Time:

This is Aswathy Balan, EPA contractor.

I'm calling regarding your submission in support of

Reg # 59639-RIG.

We have found the following deficiencies regarding:

PR Notice 86.5: Yes or No

Volume/Study Title:

\* Study #2: is missing in the application package.

Volume/Study Title:

Volume/Study Title:

Passed

Additional volumes continued on back of page: Yes or No

Application Package: Yes or No

→ 2 inert issues

→ data matrix is submitted for Technical and not for the end use product.

These deficiencies have been approved by EPA.

The corrections can be faxed to 703-305-5060/Attn: Aswathy Balan.

Second Call/Email:

If we do not receive the corrections by \_\_\_\_\_, we will process your submission, accordingly. Please direct all future calls and correspondence to the appropriate EPA Risk Manager.





09 June 2011

**Application for New End-Use Product**  
 NipsIt™ SUITE Cereals OF Seed Protectant  
 PRIA Action: R310  
 EPA Reg no. 59639-XXX

**THIS DOCUMENT AND ATTACHMENTS CONTAIN CONFIDENTIAL BUSINESS INFORMATION**

Ms. Venus Eagle (PM 01, RD)  
 Document Processing Desk  
 Office of Pesticide Programs (7505P)  
 U.S. Environmental Protection Agency  
 Room S-4900, One Potomac Yard  
 2777 South Crystal Drive  
 Arlington, VA 22202-4501

Dear Mrs. Eagle:

Valent U.S.A. Corporation (Valent) is seeking to register a new product, NipsIt™ SUITE Cereals OF Seed Protectant NOVATE Seed Protectant, for use on cereal grains as seed treatment. This new end-use product contains active ingredients: Clothianidin, Metalaxyl and Metconazole.

Components (Active ingredient)	g.ai/100 kg delivered from highest label rate of 7.5 fl.oz/100 lbs seeds	highest rate (g.ai/100kg ) registered for cereal seed treatment for on farm and commercial use
Clothianidin	15	70
<u>Metconazole</u>	2.3	2.5
<u>Metalaxyl</u>	4.5	31

Valent is pleased to submit the following paper copies of the documents listed below in support of these actions. An electronic submission of these documents will follow after the assignment of MRID numbers.



1. Administrative Documents

- EPA Application form (OPP Form no. 8570-01).
- Formulator's Exemption (EPA Form no. 8570-27).
- Data Matrix (OPP Form no. 8570-35).
- Certification with Respect to Citation of Data (OPP Form no. 8570-34).
- One copy of Material Safety Data Sheet (No 0416 rev1)
- Copies of Confidential Statement of Formula (CSF) dated 5-23 (VC-1875), 5-24 (VC-1875A), 5-25 (VC -1888).
- Five (5) printed copies of the proposed labeling.
- Data Transmittal Document which list all studies being submitted.

2. Supporting Data

- Two copies of each study report as listed in the Data Transmittal Document.
- One CD of electronic copies of the proposed labels in Adobe Acrobat PDF format.
- A Certification with Respect to Label Integrity Statement.

3. PRIA Fee

- Receipt dated: June 06, 2011. The PRIA II R310 fee is paid to support this petition (Agency tracking no. 74207958251).

If you have any questions, please contact me at (214)-784-5536 or via email:  
[sshen@valent.com](mailto:sshen@valent.com).

Sincerely,

*Lisa V. Cortes*

*for*

Sue-Chi Shen  
Project Manager  
Registration and Regulatory Affairs

Enclosures



# DATA TRANSMITTAL DOCUMENT

**ACTIVE INGREDIENT(S):** CLOTHIANIDIN, METALAXYL, METCONAZOLE  
**PRODUCT(S):** NipsIt™ SUITE Cereals OF Seed Protectant  
**EPA ID NUMBER:** 59639-XXX  
**SUBMITTER:** Valent U.S.A  
 1600 Riviera Ave  
 Walnut Creek, CA 94596  
**TRANSMITTAL DATE:** JUNE 09, 2011  
**REGULATORY ACTION SUPPORTED:** NEW END-USE PRODUCT REGISTRATION

VOLUME	GUIDELINE	STUDY	MRID
1		Title: Product Identity and Composition of NipsIt SUITE Cereals OF Seed Protectant Description of Materials Used to Produce the Product NipsIt SUITE Cereals OF Seed Protectant Description of Manufacturing Process for NipsIt SUITE Cereals OF Seed Protectant Description of Formulation Process for NipsIt SUITE Cereals OF Seed Protectant Discussion of Formation of Impurities for Process for NipsIt SUITE Cereals OF Seed Protectant Preliminary Analysis of Process for NipsIt SUITE Cereals OF Seed Protectant Certified Limits for Process for NipsIt SUITE Cereals OF Seed Protectant Enforcement Analytical Method for Process for NipsIt SUITE Cereals OF Seed Protectant Submittal of Samples for Process for NipsIt SUITE Cereals OF Seed Protectant	48505201
		Author: Evelyn J. Taylor Lab ID: 2011-10304-011 Study Completion Date: June 06, 2011 Valent Accession No.: 201100153 AB	
2	830.6302 830.6303 830.6304 830.6313 830.6314 830.6315 830.6316 830.6319 830.6321 830.7000 830.7050 830.7100 830.7200 830.7220 830.7300 830.7370 830.7520 830.7550 830.7560 830.7570 830.7840 830.7860 830.7950	Title: NipsIt SUITE Cereals OF Seed Protectant:/ Physical and Chemical Properties of V-10304 0.37 FS  Author: Nie C Lab ID: VP-37858 Study Completion Date: May 25, 2011 Valent Accession No.: 201100150	48505202



- |   |          |  |          |
|---|----------|--|----------|
| 3 | 870.1100 | Title: NipsIt SUITE Cereals OF Seed Protectant: Acute Oral Toxicity Up and Down Procedure in Rats                | 48505203 |
|   |          | Author: Lowe C<br>Lab ID: 31844; 37911<br>Study Completion Date: May 24, 2011<br>Valent Accession No.: 201100144 |          |
| 4 | 870.1200 | Title: NipsIt SUITE Cereals OF Seed Protectant: Acute Dermal Toxicity Study in Rats                              | 48505204 |
|   |          | Author: Lowe C<br>Lab ID: 31845; 37913<br>Study Completion Date: May 24, 2011<br>Valent Accession No.: 201100145 |          |
| 5 | 870.1300 | Title: NipsIt SUITE Cereals OF Seed Protectant: Acute Inhalation Toxicity Study in Rats                          | 48505205 |
|   |          | Author: Lowe C<br>Lab ID: 31846; 37915<br>Study Completion Date: May 23, 2011<br>Valent Accession No.: 201100146 |          |
| 6 | 870.2400 | Title: NipsIt SUITE Cereals OF Seed Protectant: Primary Eye Irritation Study in Rabbits                          | 48505206 |
|   |          | Author: Lowe C<br>Lab ID: 31847; 37917<br>Study Completion Date: May 23, 2011<br>Valent Accession No.: 201100147 |          |
| 7 | 870.2500 | Title: NipsIt SUITE Cereals OF Seed Protectant: Primary Skin Irritation Study in Rabbits                         | 48505207 |
|   |          | Author: Lowe C<br>Lab ID: 31848; 37919<br>Study Completion Date: May 24, 2011<br>Valent Accession No.: 201100148 |          |
| 8 | 870.2600 | Title: NipsIt SUITE Cereals OF Seed Protectant: Dermal Sensitization Study in Guinea Pigs [Buehler Method]       | 48505208 |
|   |          | Author: Lowe C<br>Lab ID: 31849; 37922<br>Study Completion Date: May 24, 2011<br>Valent Accession No.: 201100149 |          |



# DATA TRANSMITTAL DOCUMENT

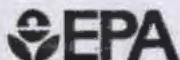
**ACTIVE INGREDIENT(S):** CLOTHIANIDIN, METALAXYL, METCONAZOLE  
**PRODUCT(S):** NipsIt™ SUITE Cereals OF Seed Protectant  
**EPA ID NUMBER:** 59639-XXX  
**SUBMITTER:** Valent U.S.A  
 1600 Riviera Ave  
 Walnut Creek, CA 94596  
**TRANSMITTAL DATE:** JUNE 09, 2011  
**REGULATORY ACTION SUPPORTED:** NEW END-USE PRODUCT REGISTRATION

VOLUME	GUIDELINE	STUDY	MRID
1		Title: Product Identity and Composition of NipsIt SUITE Cereals OF Seed Protectant Description of Materials Used to Produce the Product NipsIt SUITE Cereals OF Seed Protectant Description of Manufacturing Process for NipsIt SUITE Cereals OF Seed Protectant Description of Formulation Process for NipsIt SUITE Cereals OF Seed Protectant Discussion of Formation of Impurities for Process for NipsIt SUITE Cereals OF Seed Protectant Preliminary Analysis of Process for NipsIt SUITE Cereals OF Seed Protectant Certified Limits for Process for NipsIt SUITE Cereals OF Seed Protectant Enforcement Analytical Method for Process for NipsIt SUITE Cereals OF Seed Protectant Submittal of Samples for Process for NipsIt SUITE Cereals OF Seed Protectant	
		Author: Lab ID: Study Completion Date: Valent Accession No.:	
2	830.6302 830.6303 830.6304 830.6313 830.6314 830.6315 830.6316 830.6319 830.6321 830.7000 830.7050 830.7100 830.7200 830.7220 830.7300 830.7370 830.7520 830.7550 830.7560 830.7570 830.7840 830.7860 830.7950	Title: NipsIt SUITE Cereals OF Seed Protectant:/ Physical and Chemical Properties of V-10304 0.37 FS  Author: Nie C Lab ID: VP-37858 Study Completion Date: May 25, 2011 Valent Accession No.: 201100150	



- 3 870.1100 Title: NipsIt SUITE Cereals OF Seed Protectant:|Acute Oral Toxicity  
Up and Down Procedure in Rats  
Author: Lowe C  
Lab ID: 31844; 37911  
Study Completion Date: May 24, 2011  
Valent Accession No.: 201100144
- 4 870.1200 Title: NipsIt SUITE Cereals OF Seed Protectant:|Acute Dermal  
Toxicity Study in Rats  
Author: Lowe C  
Lab ID: 31845; 37913  
Study Completion Date: May 24, 2011  
Valent Accession No.: 201100145
- 5 870.1300 Title: NipsIt SUITE Cereals OF Seed Protectant:|Acute Inhalation  
Toxicity Study in Rats  
Author: Lowe C  
Lab ID: 31846; 37915  
Study Completion Date: May 23, 2011  
Valent Accession No.: 201100146
- 6 870.2400 Title: NipsIt SUITE Cereals OF Seed Protectant:|Primary Eye  
Irritation Study in Rabbits  
Author: Lowe C  
Lab ID: 31847; 37917  
Study Completion Date: May 23, 2011  
Valent Accession No.: 201100147
- 7 870.2500 Title: NipsIt SUITE Cereals OF Seed Protectant:|Primary Skin  
Irritation Study in Rabbits  
Author: Lowe C  
Lab ID: 31848; 37919  
Study Completion Date: May 24, 2011  
Valent Accession No.: 201100148
- 8 870.2600 Title: NipsIt SUITE Cereals OF Seed Protectant:|Dermal  
Sensitization Study in Guinea Pigs [Buehler Method]  
Author: Lowe C  
Lab ID: 31849; 37922  
Study Completion Date: May 24, 2011  
Valent Accession No.: 201100149





United States  
Environmental Protection Agency  
Washington, DC 20460

Registration  
Amendment  
☒ Other

OPP Identifier Number

## Application for Pesticide - Section I

1. Company/Product Number 59639- <del>XXX</del> <b>RIG</b>	2. EPA Product Manager Venus Eagle	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) NipsIt™ SUITE Cereals OF Seed Protectant	PM# 1	
5. Name and Address of Applicant (Include ZIP Code) Valent 1600 Riviera Ave., Suite 200, Walnut Creek, CA 94596-8025  <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

## Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input checked="" type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

A new end use product. PRIA Category R 310

## Section - III

1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
* Certification must be submitted		If "Yes" Unit Packaging wgt. _____ No. per container _____	If "Yes" Package wgt. _____ No. per container _____
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(s) Retail Container 2.5 gal and 260 gal	5. Location of Label Directions <input checked="" type="checkbox"/> On Labeling	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled <input type="checkbox"/> Other _____			

## Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Sue-Chi Shen	Title Project Manager	Telephone No. (Include Area Code) 214-78-5536	
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received  <b>(Stamped)</b>  118
2. Signature 	3. Title Project Manager		
4. Typed Name Sue-Chi Shen	5. Date 6/9 /2011		





United States  
Environmental Protection Agency  
Washington, DC 20460  
**Formulator's Exemption Statement**  
(40 CFR 152.85)

Applicant's Name and Address  Valent U.S.A. Corporation 1600 Riviera, Suite 200 Walnut Creek, CA 94596	EPA File Symbol/Registration Number 59639-XXX
	Product Name NipsIt™ SUITE Cereals OF Seed Protectant
	Date of Confidential Statement of Formula (EPA Form 8570-4) 05/23/2011

As an authorized representative of the applicant for registration of the product identified above, I certify that:

(1) This product contains the following active ingredient(s):

Clothianidin - Valent

Metalaxyl - [REDACTED]

Metconazole - [REDACTED]

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another person and meets the requirements of 40 CFR section 158.50(e)(2) or (3).

(3) Indicate by checking (A) or (B) below which paragraph applies:

☒ (A) An accurate Confidential Statement of Formula (EPA FORM 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

☐ (B) The Confidential Statement of Formula (CSF)(EPA Form 8570-4) referenced above and on file with the EPA is complete, current, an accurate and contains the information required on the current CSF.

(4) The following active ingredients in this product qualify for the formulator's exemption.

Source		
Active Ingredient	Product Name	Registration Number
Clothianidin	Clothianidin Technial	59639-173
Metalaxyl	[REDACTED]	[REDACTED]
Metconazole	[REDACTED]	[REDACTED]
Signature 	Name and Title Sue-Chi Shen, Project Manager	Date 06/06/2011

EPA Form 8570-27 (Rev. 06-2004)

\*Product Source Information may be Subject to  
Confidential Treatment\*

Copy 1 - EPA  
Copy 2 - Applicant copy





**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
**1200 Pennsylvania Avenue, N.W.**  
**WASHINGTON, D.C. 20460**

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, Collection Strategies Division (2822T), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. Do not send the completed form to this address.

**Certification with Respect to Citation of Data**

Applicant's/Registrant's Name, Address, and Telephone Number  
 Valent USA Corp. 1600 Riviera Drive, Suite 200, Walnut Creek, CA 94596

EPA Registration Number/File Symbol  
 59639-XXX

Active Ingredient(s) and/or representative test compound(s)  
 Clothianidin, Metalaxyl, Metconazole

Date  
 6/9/2011

General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158)  
 Seed treatment

Product Name  
 Nipsit™ SUITE Cereals OF Seed Protectant

**NOTE:** If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

**SECTION I: METHOD OF DATA SUPPORT** (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

**SECTION II: GENERAL OFFER TO PAY**

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

**SECTION III: CERTIFICATION**

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature

*Lisa V. Cortez*

Date

6/9/2011

Typed or Printed Name and Title

Sue-Chi Shen, Project Manager



## Online Payment

## Step 3: Confirm Payment

1 | 2 | 3

Thank you.

Your transaction has been successfully completed.

## Pay.gov Tracking Information

Application Name: PRIA Service Fees

Pay.gov Tracking ID: 253I757A

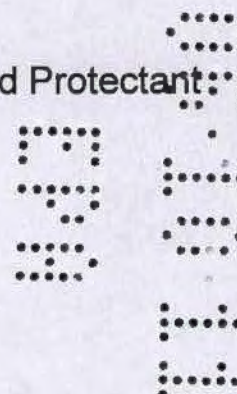
Agency Tracking ID: 74207958251

Transaction Date and Time: 06/06/2011 18:58 EDT

## Payment Summary

Address Information	Account Information	Payment Information
Account Holder Valent Name: Regulatory 1600 Riviera Billing Address: Ave Billing Address 2: Suite 200 City: Walnut Creek State / Province: CA Zip / Postal Code: 94596 Country: USA	Card Type: Visa Card Number: *****8669 Decision Number: Registration Number: 59639- Company VALENT U.S.A. Name: CORPORATION Company Number: 9252562712 Action Code: R310	Payment Amount: \$4,807.00 Transaction Date 06/06/2011 and Time: 18:58 EDT

PRIA Category R310: NipsIt™ SUITE Cereals OF Seed Protectant  
New end-use or manufacturing product







# Material Safety Data Sheet

**NipsIt™ SUITE Cereals OF Seed Protectant**

## 1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

**PRODUCT NAME:** NipsIt™ SUITE Cereals OF Seed Protectant  
**EPA REGISTRATION NUMBER:** Not Registered  
**PRODUCT CODE:** Not established  
**VC NUMBER(S):** 1875 and 1888

**MANUFACTURER/DISTRIBUTOR**  
VALENT U.S.A. CORPORATION  
P.O. Box 8025  
1600 Riviera Avenue, Suite 200  
Walnut Creek, CA 94596-8025

**EMERGENCY TELEPHONE NUMBERS**  
HEALTH EMERGENCY OR SPILL (24 hr):  
(800) 892-0099  
TRANSPORTATION (24 hr.): CHEMTREC  
(800) 424-9300 or (202) 483-7616

**PRODUCT INFORMATION**  
AGRICULTURAL PRODUCTS: (800) 682-5368

The current MSDS is available through our website ([www.valent.com](http://www.valent.com)), or by calling the product information numbers listed above.

## 2. HAZARDS IDENTIFICATION

**This product should pose no health concerns through normal use.**

**No signal word required.**

- Keep out of reach of children.
- Wash hands thoroughly with soap and water after handling.

### POTENTIAL HEALTH EFFECTS

**Acute Toxicity (Primary Routes of Exposure):** None known

**Chronic Toxicity (including cancer):** The active ingredient did not cause cancer in long-term animal studies. This product is not listed as a carcinogen by the National Toxicology Program (NTP), the International Agency for Research on Cancer (IARC), the Occupational Safety and Health Administration (OSHA) or ACGIH.

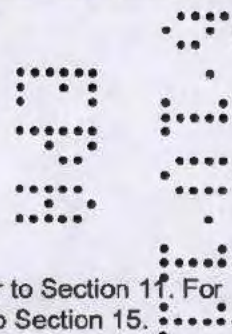
**Developmental Toxicity (birth defects):** Not considered a developmental hazard.

**Reproductive Toxicity:** Not considered a reproductive hazard.

**Signs and Symptoms of Systemic Effects:** No Data Available

**Potentially Aggravated Medical Conditions:** None known

For complete discussion of the toxicology data from which this evaluation was made, refer to Section 11. For Ecotox/Environmental Information, refer to Section 12. For Regulatory Information, refer to Section 15.



## 3. COMPOSITION/INFORMATION ON INGREDIENTS

**Emergency Telephone:** (800) 892-0099  
**REVISION NUMBER:** 1

**MSDS NO.:** 0416  
**REVISION DATE:** 06/02/2011



**3. COMPOSITION/INFORMATION ON INGREDIENTS**

Chemical Name	CAS Number	Weight/ Percent	Purpose
Clothianidin [(E)-1-(2-chloro-1,3-thiazol-5-ylmethyl)-3-methyl-2-nitroguanidine]	210880-92-5	2.7 - 3.1	Active Ingredient
Metconazole (5-[(4-chlorophenyl)methyl]-2,2-dimethyl-1-(1H-1,2,4-triazol-1-ylmethyl)cyclopentanol)	125116-23-6	0.40 - 0.48	Active Ingredient
Metaxyl (N-(2,6-dimethylphenyl)-N-(methoxyacetyl)alaninemethyl ester)	57837-19-1	0.79 - 0.97	Active Ingredient
Other ingredients	Various CAS#s	94.5 - 97	Other Ingredients

Other ingredients, which are maintained as trade secrets, are any substances other than an active ingredient contained in this product. Some of these may be hazardous, but their identity is withheld because they are considered trade secrets. The hazards associated with the other ingredients are addressed in this document. Specific information on other ingredients for the management of exposures, spills, or safety assessments can be obtained by a treating physician or nurse by calling (800) 682-5368 at any time

**4. FIRST AID MEASURES****EMERGENCY NUMBER (800) 892-0099**

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact **1-800-892-0099** for emergency medical treatment information.

**EYE CONTACT:**

Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.

**SKIN CONTACT:**

Wash with soap and water. Remove and wash contaminated clothing separately.

**INGESTION:**

No emergency medical treatment necessary.

**INHALATION:**

Seek fresh air.

**NOTES TO PHYSICIAN:**

None

**5. FIRE FIGHTING MEASURES**

**FLASH POINT:** > 200°F (93° C)  
**FLASH POINT METHOD:** Not applicable  
**AUTOIGNITION:** No data available  
**EXTINGUISHING MEDIA:** Water fog, carbon dioxide, foam, dry chemical

**FLAMMABLE LIMITS IN AIR - LOWER (%):**  
**FLAMMABLE LIMITS IN AIR - UPPER (%):**

Not applicable  
Not applicable

**NFPA RATING:**

Health: 0  
Flammability: 0  
Reactivity: 0  
Special: None

**Emergency Telephone:** (800) 892-0099  
**REVISION NUMBER:** 1

**MSDS NO.:** 0416  
**REVISION DATE:** 06/02/2011



(Least-0, Slight-1, Moderate-2, High-3, Extreme-4). These values are obtained using professional judgement. Values were not available in the guidelines or published evaluations prepared by the National Fire Protection Association, NFPA.

**FIRE FIGHTING INSTRUCTIONS:** Products of combustion from fires involving this material may be toxic. Avoid breathing smoke and mists. Avoid personnel and equipment contact with fallout and runoff. Minimize the amount of water used for fire fighting. Do not enter any enclosed area without full protective equipment, including self-contained breathing equipment. Contain and isolate runoff and debris for proper disposal. Decontaminate personal protective equipment and fire fighting equipment before reuse.

**HAZARDOUS DECOMPOSITION PRODUCTS:** May form toxic materials such as: Carbon dioxide, hydrogen chloride, oxides of sulfur, Oxides of Nitrogen, Carbon monoxide, various hydrocarbons, etc.

## 6. ACCIDENTAL RELEASE MEASURES

**VALENT EMERGENCY PHONE NUMBER: (800) 892-0099**

**CHEMTREC EMERGENCY PHONE NUMBER: (800) 424-9300**

### OBSERVE PRECAUTIONS IN SECTION 8: PERSONAL PROTECTION

Stop the source of the spill if safe to do so. Contain the spill to prevent further contamination of the soil, surface water, or ground water. For additional spill response information refer to the North American Emergency Response Guidebook.

**UN/NA NUMBER:** Not applicable

**EMERGENCY RESPONSE GUIDEBOOK NO.:** Not applicable

#### FOR SPILLS ON LAND:

**CONTAINMENT:** Avoid runoff into storm sewers and ditches which lead to waterways. Contain spilled liquids with dry sorbents.

**CLEANUP:** Clean up spill immediately. Absorb spill with inert material (such as dry sand or earth), then place in a chemical waste container. Wash area with soap and water. Pick up wash liquid with additional absorbent and place in a chemical waste container.

#### FOR SPILLS IN WATER:

**CONTAINMENT:** This material will disperse or dissolve in water. Stop the source of the release. Contain and isolate to prevent further release into soil, surface water and ground water.

**CLEANUP:** Clean up spill immediately. Absorb spill with inert material. Remove contaminated water for treatment or disposal.

## 7. HANDLING AND STORAGE

**END USER MUST READ AND OBSERVE ALL PRECAUTIONS ON PRODUCT LABEL.**

#### HANDLING:

Keep pesticide in original container. Do not contaminate food or feed. Do not put concentrate into food or drink containers. Do not dilute concentrate in food or drink containers.

Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

Keep container tightly closed. Stable at normal temperatures and storage conditions in closed original package.

#### STORAGE:

Do not reuse empty container. Open dumping is prohibited. Store in a cool, dry place, out of direct sunlight. Do not store at temperatures below 32°F. If the product is exposed to temperatures below 32°F, thaw at room temperature to 50°F or warmer and shake gently to unify the product.



**8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

**END USER MUST READ AND OBSERVE ALL PRECAUTIONS ON PRODUCT LABEL.**

**EYES & FACE:** Not required with normal use, unless label directs otherwise.

**RESPIRATORY PROTECTION:** Not required with normal use, unless label directs otherwise.

**SKIN & HAND PROTECTION:** Not required with normal use, unless label directs otherwise. Wash hands before breaks and at the end of work.

**ENGINEERING CONTROLS:** Use in a well ventilated area.

**EXPOSURE LIMITS**

Chemical Name	ACGIH Exposure Limits	OSHA Exposure Limits	Manufacturer's Exposure Limits
Clothianidin [(E)-1-(2-chloro-1,3-thiazol-5-ylmethyl)-3-methyl-2-nitroguanidine]	None	None	None
Metconazole (5-[(4-chlorophenyl)methyl]-2,2-dimethyl-1-(1H-1,2,4-triazol-1-ylmethyl)cyclopentanol)	None	None	None
Metaxyl (N-(2,6-dimethylphenyl)-N-(methoxyacetyl)alaninemethyl ester)	None	None	None
Other ingredients	None	None	None

**9. PHYSICAL AND CHEMICAL PROPERTIES****PHYSICAL FORM:****COLOR:****ODOR:****FLASH POINT:****FLASH POINT METHOD:****DENSITY:****pH:****VISCOSITY:****CORROSION CHARACTERISTICS:****SOLUBILITY:**

Liquid

Opaque Red

Paint-like, Latex

&gt; 200°F (93° C)

Not applicable

1.05 g/mL @ 20° C

5.94 @ 25° C (1% dilution in water)

73.0 cP @ 20° C; 58.9 cP @ 40° C

No data available

Miscible/dispersible in water

**10. STABILITY AND REACTIVITY****CHEMICAL STABILITY:****OXIDATION/REDUCTION PROPERTIES:****EXPLODABILITY:****HAZARDOUS DECOMPOSITION PRODUCTS:****HAZARDOUS POLYMERIZATION :**

Stable at normal ambient temperatures.

Not reactive with water, monoammonium phosphate, zinc, and potassium permanganate.

Not expected to be explosive

May form toxic materials such as: Carbon dioxide, hydrogen chloride, oxides of sulfur, Oxides of Nitrogen, Carbon monoxide, various hydrocarbons, etc.

Will not occur



## 11. TOXICOLOGICAL INFORMATION

## ACUTE TOXICITY:

The following information for NipsIt SUITE Cereals OF Seed Protectant

Oral Toxicity LD <sub>50</sub> (rats)	> 5000 mg/kg	EPA Tox Category	IV
Dermal Toxicity LD <sub>50</sub> (rats)	> 5000 mg/kg	EPA Tox Category	IV
Inhalation Toxicity LC <sub>50</sub> (rats)	> 2.06 mg/L	EPA Tox Category	IV
Eye Irritation (rabbits)	Minimally irritating	EPA Tox Category	IV
Skin Irritation (rabbits)	Slightly irritating	EPA Tox Category	IV
Skin Sensitization (guinea pigs)	Non-sensitizer	EPA Tox Category	Not applicable

## CARCINOGEN CLASSIFICATION

Chemical Name	IARC - Group 1 (carcinogenic to humans)	IARC - Group 2A (Probably carcinogenic)	IARC - Group 2B (Possibly carcinogenic)	NTP Carcinogen List
Clothianidin [(E)-1-(2-chloro-1,3-thiazol-5-ylmethyl)-3-methyl-2-nitroguanidine]	No	No	No	Not listed
Other ingredients	No	No	No	Not listed
Metconazole (5-[(4-chlorophenyl)methyl]-2,2-dimethyl-1-(1H-1,2,4-triazol-1-ylmethyl)cyclopentanol)	No	No	No	Not listed
Metaxyl (N-(2,6-dimethylphenyl)-N-(methoxyacetyl)alaninemethyl ester)	No	No	No	Not listed

## TOXICITY OF CLOTHIANIDIN TECHNICAL

**SUBCHRONIC:** The NOEL in a 3-month rat feeding study with Clothianidin Technical was 27.9 mg/kg/day (male) and 34.0 mg/kg/day (female). The NOEL in a 90-day dog feeding study was 19.3 mg/kg/day (male) and 21.2 mg/kg/day (female). In a subchronic dermal study with rats, the NOAEL is > 1,000 mg/kg/day.

**CHRONIC/CARCINOGENICITY:** The Clothianidin NOEL for a 2-year rat study was 9.7 mg/kg/day (female); for a 18-month mouse study was 47.2 mg/kg/day (male) and for a 12-month dog study was 7.8 mg/kg/day (male). The principal target organs were the glandular stomach, kidney, ovary, and liver. No oncogenic effects were observed in the 2-year rat or 18-month mouse feeding studies.

**NEUROTOXICITY:** Clothianidin is not a neural toxin.

**DEVELOPMENTAL TOXICITY:** No teratogenic effects on rats or rabbits were observed. Transient developmental effects (delayed ossification) were observed in rabbits at maternally toxic doses (100 mg/kg/d). The technical material is fetotoxic in animal studies at maternally toxic doses.

**REPRODUCTION:** No reproductive effects were observed in rats at the highest dose tested (2500 ppm).

**MUTAGENICITY:** *In vivo* tests have demonstrated that the technical material is not mutagenic. Some *in-vitro* tests were positive for mutagenicity. The observed effects *in-vitro* were due to cytotoxic effects. The weight-of-evidence from the *in vivo* whole animal tests suggest that this product does not present a mutagenic hazard.

For a summary of the potential for adverse health effects from exposure to this product, refer to Section 2. For information regarding regulations pertaining to this product, refer to Section 15.



**12. ECOLOGICAL INFORMATION**

**AVIAN TOXICITY:** The following information is based upon component(s) of this material.  
96-hr Oral Bobwhite quail: > 780 mg/kg  
96-hr Oral Mallard duck: = 503 mg/kg  
96-hr Dietary Mallard duck: > 5,200 ppm

**AQUATIC ORGANISM TOXICITY:** This product is toxic to aquatic invertebrates.

**OTHER NON-TARGET ORGANISM TOXICITY:** Honeybee 48-hour oral LD<sub>50</sub>: = 0.044ug (microgram)/bee  
Honeybee 48-hour contact LD<sub>50</sub>: = 0.004 ug (microgram)/bee  
Earthworm 7-day LC<sub>50</sub>: = 19 mg/kg dry soil

**13. DISPOSAL CONSIDERATIONS**

**END USERS MUST DISPOSE OF ANY UNUSED PRODUCT AS PER THE LABEL RECOMMENDATIONS.**

**DISPOSAL METHODS:** Check government regulations and local authorities for approved disposal of this material.  
Dispose in accordance with applicable laws and regulations.

**14. TRANSPORT INFORMATION**

<b>UN/NA NUMBER:</b>	Not applicable
<b>DOT (ground) SHIPPING NAME:</b>	Pesticides, liquid, non-regulated
<b>TECHNICAL NAME (hazardous material):</b>	Not applicable
<b>HAZARD CLASS:</b>	Not applicable
<b>PACKING GROUP:</b>	Not applicable
<b>DOT REPORTABLE QUANTITY (RQ):</b>	Not applicable
<b>REMARKS:</b>	None
<b>EXEMPTION REQUIREMENT:</b>	None
<b>EMERGENCY RESPONSE GUIDEBOOK NO.:</b>	Not applicable
<b>MARINE POLLUTANT:</b>	Not applicable under US regulations 49CFR

**15. REGULATORY INFORMATION**

**PESTICIDE REGULATIONS:** All pesticides are governed under FIFRA (Federal Insecticide, Fungicide, and Rodenticide Act). Therefore, the regulations presented below are pertinent only when handled outside of the normal use and applications of pesticides. This includes waste streams resulting from manufacturing/formulation facilities, spills or misuse of products, and storage of large quantities of products containing hazardous or extremely hazardous substances.

**U.S. FEDERAL REGULATIONS:**

Ingredients in this product are reviewed against an inclusive list of federal regulations. Therefore, the user should consult appropriate authorities. The federal regulations reviewed include: Clean Water Act, SARA, CERCLA, RCRA, DOT, TSCA and OSHA. If no components or information is listed in the space below this paragraph, then none of the regulations reviewed are applicable.

**SARA (311, 312):**

Immediate Health: No

Emergency Telephone: (800) 892-0099  
REVISION NUMBER: 1

MSDS NO.: 0416  
REVISION DATE: 06/02/2011



Chronic Health: No  
Fire: No  
Sudden Pressure: No  
Reactivity: No

**STATE REGULATIONS:**

Each state may promulgate standards more stringent than the federal government. This section cannot encompass an inclusive list of all state regulations. Therefore, the user should consult state or local authorities. The state regulations reviewed include: California Proposition 65, California Directors List of Hazardous Substances, Massachusetts Right to Know, Michigan Critical Materials List, New Jersey Right to Know, Pennsylvania Right to Know, Rhode Island Right to Know and the Minnesota Hazardous Substance list. For Washington State Right to Know, see Section 8 for Exposure Limit information. For Louisiana Right to Know refer to SARA information listed under U.S. Regulations above. If no components or information is listed in the space below this paragraph, then none of the regulations reviewed are applicable.

**Metconazole (5-[(4-chlorophenyl)methyl]-2,2-dimethyl-1-(1H-1,2,4-triazol-1-ylmethyl)cyclopentanol)**  
NJ Right To Know Listed

For information regarding potential adverse health effects from exposure to this product, refer to Sections 2 and 11.

**16. OTHER INFORMATION**

**REASON FOR ISSUE:** New Product;  
**MSDS NO.:** 0416  
**EPA REGISTRATION NUMBER:** Not Registered  
**REVISION NUMBER:** 1  
**REVISION DATE:** 06/02/2011  
**SUPERCEDES DATE:** NA  
**RESPONSIBLE PERSON(S):** Valent U.S.A. Corporation, Corporate EH&S, (925) 256-2803

This Material Safety Data Sheet (MSDS) serves different purposes than and DOES NOT REPLACE OR MODIFY THE EPA-APPROVED PRODUCT LABELING (attached to and accompanying the product container). This MSDS provides important health, safety, and environmental information for employers, employees, emergency responders and others handling large quantities of the product in activities generally other than product use, while the labeling provides that information specifically for product use in the ordinary course.

Use, storage and disposal of pesticide products is regulated by the EPA under the authority of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) through the product labeling. All necessary and appropriate precautionary, use, storage, and disposal information is set forth on that labeling. It is a violation of federal law to use a pesticide product in any manner not prescribed on the EPA-approved label.

The information in this MSDS is based on data available to us as of the revision date given herein, and believed to be correct. Contact Valent U.S.A. Corporation to confirm if you have the most current MSDS.

Judgements as to the suitability of information herein for the individual's own use or purposes are necessarily the individual's own responsibility. Although reasonable care has been taken in the preparation of such information, Valent extends no warranties, makes no representations, and assumes no responsibility as to the accuracy or suitability of such information for application to the individual's purposes or the consequences of its use.

2011 Valent U.S.A. Corporation

**Emergency Telephone:** (800) 892-0099  
**REVISION NUMBER:** 1

**MSDS NO.:** 0416  
**REVISION DATE:** 06/02/2011



# R 310

End Use (EP) or Manufacturing Use (MP) product or Technical Grade of the Active Ingredient (TGA).  
Must submit Group A and B product chemistry data for each proposed product unless it's a 100% identical (repack): YES or (NO) (circle one)

Guideline No.	Group A: Product Chemistry Data Study Title	EP Data Submitted		MP Data Submitted		TGA	
		Yes	No	Yes	No	Yes	No
830.1550	Product Identity & Composition	X					
830.1600	Description of materials used to produce the product	X					
830.1650	Description of formulation process	X					
830.1670	Discussion on the formation of impurities	X					
830.1700	Preliminary analysis		X				
830.1750	Certified limits (158.345)	X					
830.1800	Enforcement analytical method	X					

NA

Guideline No.	Group B: Product Chemistry Data Study Title	EP Data Submitted		MP Data Submitted		TGA	
		Yes	No	Yes	No	Yes	No
830.6302	Color	X					
830.6303	Physical State	X					
830.6304	Odor	X					
830.6313	Stability to normal and elevated temperatures metal and metal ions						
830.6314	Oxidation/Reduction (Chemical incompatibility)		X				
830.6315	Flammability		X				
830.6316	Explosibility		X				
830.6317	Storage stability		X				
830.6319	Miscibility		X				
830.6320	Corrosion Characteristics		X				
830.6321	Dielectric Breakdown Voltage		X				
830.7000	pH	X					
830.7050	UV/ Visible Absorption						
830.7100	Viscosity	X					
830.7200	Melting Point						
830.7220	Boiling Point						
830.7300	Density	X					
830.7370	Dissociation Constant						
830.7550	Partition Coefficient						
830.7840	Water Solubility						
830.7950	Vapor Pressure						

NA

NA

NA

in progress

NA

in progress

NA

Grayed out = data not required



## R 310

New products must either: 1) supply the product specific acute toxicity 6 pack data (listed below), or 2) provide a bridging rationale document. The bridging document directs OPP to use a currently registered set of 6 acute toxicity data and label; instead of submitting product specific data.

Guideline No.	Acute toxicity (6 pack) Study Title	Data submitted		Cited	
		Yes	No	Yes	No
870.1100	Acute Oral (LD50)	X			
870.1200	Acute Dermal (LD50)	X			
870.1300	Acute Inhalation (LC50)	X			
870.2400	Acute Eye Irritation	X			
870.2500	Acute Dermal Irritation	X			
870.2600	Dermal Sensitization	X			

Efficacy – which guideline is used depends on the proposed label use

Guideline No.	Study Title	Data submitted		Cited		Comments
		Yes	No	Yes	No	
810.3100	Soil Treatments for Imported Fire Ants					
810.3200	Livestock, Poultry, Fur and Wool-Bearing Animal Treatments					
810.3300	Treatments to Control Pests of Humans and Pets					
810.3400	Mosquito, Black Fly, and Biting Midge (Sand Fly) Treatments					
810.3500	Premises Treatments					
810.3600	Structural Treatments					
810.3800	Methods for Efficacy Testing of Termite Baits					



Date:  
09 JUNE 2011

Product:  
NipsIt™ SUITE Cereals OF Seed Protectant

Active Ingredient:  
CLOTHIANIDIN, METALAXYL, METCONAZOLE

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
1200 Pennsylvania Avenue  
WASHINGTON, D.C. 20460-0001

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: 09 JUNE 2011

EPA Reg No./ File Symbol: 59639-RIG

Total Pages = 02


Applicant's/ Registrant's Name & Address

VALENT U.S.A. CORPORATION

Product: NipsIt™ SUITE Cereals OF Seed Protectant

1600 Riviera Avenue, Suite 200 Walnut Creek, CA 94596

Ingredients: CLOTHIANIDIN, METALAXYL, METCONAZOLE

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.1550, 830.1600, 830.1620, 830.1650, 830.1670, 830.1700, 830.1750, 830.1800, 830.1900	Product Identity and Composition of NipsIt SUITE Cereals OF Seed Protectant Description of Materials Used to Produce the Product NipsIt SUITE Cereals OF Seed Protectant Description of Manufacturing Process for NipsIt SUITE Cereals OF Seed Protectant Description of Formulation Process for NipsIt SUITE Cereals OF Seed Protectant Discussion of Formation of Impurities for Process for NipsIt SUITE Cereals OF Seed Protectant Preliminary Analysis of Process for NipsIt SUITE Cereals OF Seed Protectant Certified Limits for Process for NipsIt SUITE Cereals OF Seed Protectant Enforcement Analytical Method for Process for NipsIt SUITE Cereals OF Seed Protectant Submittal of Samples for Process for NipsIt SUITE Cereals OF Seed Protectant		Valent U.S.A. Corporation	OWN	ACCNO: 201100153A
830.6302, 830.6303, 830.6304, 830.6313, 830.6314, 830.6315, 830.6316, 830.6319, 830.6321, 830.7000, 830.7050, 830.7100, 830.7200, 830.7220, 830.7300, 830.7370, 830.7520, 830.7550, 830.7560, 830.7570, 830.7840, 830.7860, 830.7950	NipsIt SUITE Cereals OF Seed Protectant:/ Physical and Chemical Properties of V-10304 0.37 FS 		Valent U.S.A. Corporation	OWN	ACCNO: 201100150



Date:  
09 JUNE 2011

Product:  
NipsIt™ SUITE Cereals OF Seed Protectant

Active Ingredient:  
CLOTHIANIDIN, METALAXYL, METCONAZOLE

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
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Date: 09 JUNE 2011

EPA Reg No./ File Symbol: 59639-RIG

Total Pages = 02

Applicant's/ Registrant's Name & Address

VALENT U.S.A. CORPORATION

Product: NipsIt™ SUITE Cereals OF Seed Protectant

1600 Riviera Avenue, Suite 200 Walnut Creek, CA 94596

Ingredients: CLOTHIANIDIN, METALAXYL, METCONAZOLE

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.1100	NipsIt SUITE Cereals OF Seed Protectant:Acute Oral Toxicity Up and Down Procedure in Rats		Valent U.S.A. Corporation	OWN	ACCNO: 201100144
870.1200	NipsIt SUITE Cereals OF Seed Protectant:Acute Dermal Toxicity Study in Rats		Valent U.S.A. Corporation	OWN	ACCNO: 201100145
870.1300	NipsIt SUITE Cereals OF Seed Protectant:Acute Inhalation Toxicity Study in Rats		Valent U.S.A. Corporation	OWN	ACCNO: 201100146
870.2400	NipsIt SUITE Cereals OF Seed Protectant:Primary Eye Irritation Study in Rabbits		Valent U.S.A. Corporation	OWN	ACCNO: 201100147
870.2500	NipsIt SUITE Cereals OF Seed Protectant:Primary Skin Irritation Study in Rabbits		Valent U.S.A. Corporation	OWN	ACCNO: 201100148
870.2600	NipsIt SUITE Cereals OF Seed Protectant:Dermal Sensitization Study in Guinea Pigs [Buehler Method]		Valent U.S.A. Corporation	OWN	ACCNO: 201100149
Signature	Name and Title:			Date	
	SUE-CHI SHEN REGULATORY PROJECT MANAGER			09 JUNE 2011	



Date:  
09 JUNE 2011

Product:  
NipsIt™ SUITE Cereals OF Seed Protectant

Active Ingredient:  
CLOTHIANIDIN, METALAXYL, METCONAZOLE

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VALENT U.S.A. CORPORATION

Product: NipsIt™ SUITE Cereals OF Seed Protectant

1600 Riviera Avenue, Suite 200 Walnut Creek, CA 94596

Ingredients: CLOTHIANIDIN, METALAXYL, METCONAZOLE

Guideline Reference

Number

Guideline Study Name

MRID Number

Submitter

Status

Note

Valent U.S.A.  
Corporation

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ACCNO:  
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Valent U.S.A.  
Corporation

OWN

ACCNO:  
201100150



Date:  
09 JUNE 2011

Product:  
NipsIt™ SUITE Cereals OF Seed Protectant

Active Ingredient:  
CLOTHIANIDIN, METALAXYL, METCONAZOLE

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Product: NipsIt™ SUITE Cereals OF Seed Protectant

Ingredients: CLOTHIANIDIN, METALAXYL, METCONAZOLE

Guideline Reference

Number

Guideline Study Name

MRID Number

Submitter

Status

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Corporation

OWN  
ACCNO:  
201100145

Valent U.S.A.  
Corporation

OWN  
ACCNO:  
201100146

Valent U.S.A.  
Corporation

OWN  
ACCNO:  
201100147

Valent U.S.A.  
Corporation

OWN  
ACCNO:  
201100148

Valent U.S.A.  
Corporation

OWN  
ACCNO:  
201100149

Signature

003

hisal. Cortes

for

Name and Title:

SUE-CHI SHEN  
REGULATORY PROJECT MANAGER

Date

09 JUNE 2011

11:21:00



Date:  
09 JUNE 2011

Product:  
CLOTHIANIDIN TECHNICAL

Active Ingredient:  
CLOTHIANIDIN

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DATA MATRIX

Date: JUNE 09, 2011

EPA Reg No./ File Symbol: 59639-173

Total Pages = 135

Applicant's/Registrant's Name & Address VALENT U.S.A. CORPORATION  
1600 Riviera Avenue, Suite 200 Walnut Creek, CA 94596

Product: CLOTHIANIDIN TECHNICAL

Ingredient: CLOTHIANIDIN

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.1800 830.7200 830.7220 830.7300 830.7950 830.6302 830.6304 830.7050 830.7840 830.7570 830.7370 830.6315 830.6316 830.6314 830.6317 830.7000 830.6313 830.6319 830.6320 830.7520	Fontaine, L. (2001) Product Chemistry of Clothianidin Technical: Lab Project Number: BR 2068: 2005-0009101-99E: ANR-01701. Unpublished study prepared by Bayer Corporation. 462 p.	45422301	Sumitomo Chemical Company, Ltd	EXC	
830.6316 830.1800 830.1750 830.1700 830.1670 830.1620 830.1600 830.1550 830.1550	Fontaine, L. (2001) Product Chemistry of Clothianidin Technical: Lab Project Number: BR 2069: ANR 01101: ANR-01201. Unpublished study prepared by Bayer Corporation. 830 p.	45422302	Sumitomo Chemical Company, Ltd	EXC	
163-1	[14C]TI-435: Adsorption/Desorption in Soil	45422311	Sumitomo Chemical Company, Ltd	EXC	
163-1	Time Dependent Sorption of TI-435 in Two Different Soils	45422312	Sumitomo Chemical Company, Ltd	EXC	
163-1	Adsorption/Desorption of 14C-MNG, a Degradate of TI-435, on Five Different Soils	45422313	Sumitomo Chemical Company, Ltd	EXC	
163-1	Adsorption/Desorption of 14C-TZNG, a Degradate of TI-435, on Five Different Soils	45422314	Sumitomo Chemical Company, Ltd	EXC	



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Product:  
CLOTHIANIDIN TECHNICAL

Active Ingredient:  
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Total Pages = 5

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Product: CLOTHIANIDIN TECHNICAL

Ingredient: CLOTHIANIDIN

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
163-1	Adsorption/Desorption of 14C-TZMU, a Degradate of TI-435, on Five Different Soils	45422315	Sumitomo Chemical Company, Ltd	EXC	
163-1	Adsorption/Desorption of 14C-TMG, a Degradate of TI-435, on Five Different Soils	45422316	Sumitomo Chemical Company, Ltd	EXC	
161-1	(14C)TI-435: Hydrolytic Stability	45422317	Sumitomo Chemical Company, Ltd	EXC	
161-2	Photolysis of [Nitroimino-14C]TI-435 and [Thiozoyl-2-14C] TI-435 in Sterile Aqueous Buffer Solution	45422318	Sumitomo Chemical Company, Ltd	EXC	
161-2	Photolysis of TI-435 in Natural US Water	45422319	Sumitomo Chemical Company, Ltd	EXC	
None	Schad, T. (2000) Calculation of Half-lives of TI-435 and its Main Metabolites Generated by Photolysis in Sterile Aqueous Buffer Solution: Lab Project Number: P668 00 6756: 110124: MR-121/00. Unpublished study prepared by Bayer Ag. 28 p.	45422320	Sumitomo Chemical Company, Ltd	EXC	
161-2	Calculation of Half-lives of TI-435 and its Main Metabolites Generated by Photolysis in Natural Water	45422321	Sumitomo Chemical Company, Ltd	EXC	
161-2	Determination of the Quantum Yield and Assessment of the Environmental Half-Life of the Direct Photodegradation of TI-435 in Water	45422322	Sumitomo Chemical Company, Ltd	EXC	



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Active Ingredient:  
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Date: JUNE 09, 2011	EPA Reg No./ File Symbol: 59639-173	Total Pages = 55
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Ingredient: CLOTHIANIDIN

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
None	Photolysis of [Guanidine-14C]TI-435 on Soil Surface	45422323	Sumitomo Chemical Company, Ltd	EXC	
162-3	Aerobic Degradation and Metabolism of TI-435 in Water / Sediment System	45422324	Sumitomo Chemical Company, Ltd	EXC	
162-1	Aerobic Degradation and Metabolism of TI-435 in Four Soils	45422325	Sumitomo Chemical Company, Ltd	EXC	
162-1	Aerobic Degradation and Metabolism of TI-435 in Six Soils	45422326	Sumitomo Chemical Company, Ltd	EXC	
162-1	Degradation of 14C-MNG, a Degradate of TI-435, in Three Different Soils	45422327	Sumitomo Chemical Company, Ltd	EXC	
162-1	Degradation of 14C-TZNG, a Degradate of TI-435, in Three Different Soils	45422328	Sumitomo Chemical Company, Ltd	EXC	
162-3	Anaerobic Aquatic Metabolism for the Active Ingredient TI-435	45422330	Sumitomo Chemical Company, Ltd	EXC	
850.1035	TI-435 Technical: A 96-Hour Flow-Through Acute Toxicity Test with the Saltwater Mysid (Mysidopsis bahia)	45422403	Sumitomo Chemical Company, Ltd	EXC	
850.1025	TI-435 Technical: Oyster, Acute Toxicity Test (Shell Deposition), Limit Test, Flow-Through, 96h	45422404	Sumitomo Chemical Company, Ltd	EXC	
850.1350	TI-435 Technical: A Flow-Through Life-Cycle Toxicity Test with the Saltwater Mysid (Mysidopsis bahia)	45422405	Sumitomo Chemical Company, Ltd	EXC	



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Active Ingredient:  
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Ingredient: CLOTHIANIDIN

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
850.1075	TI 435 Technical - Fish (Rainbow Trout) Acute Toxicity Test, 96 h, Limit test	45422406	Sumitomo Chemical Company, Ltd	EXC	
850.1075	TI-435 Technical: Fish (Sheepshead minnow), Acute Toxicity, Limit Test, 96h, semi-static	45422411	Sumitomo Chemical Company, Ltd	EXC	
72-4	TI-435 Technical: Daphnia magna Reproduction Test (21 d)	45422412	Sumitomo Chemical Company, Ltd	EXC	
850.1790	TI-435: Comparative Acute Toxicity of Chronomus riparius with TZMU, MU, TZNG and MNG	45422414	Sumitomo Chemical Company, Ltd	EXC	
71-1	Johnson, A. (1998) TI-435 Technical Acute Oral Toxicity (LD50) to Bobwhite Quail: Lab Project Number: TDA 232: 110016. Unpublished study prepared by Huntingdon Life Sciences, Ltd. 47 p.	45422417	Sumitomo Chemical Company, Ltd	EXC	
71-1	Gallagher, S.; Beavers, J. (2000) TI-435 Technical: An Acute Oral Toxicity Study with the Japanese Quail: Lab Project Number: 197-128: 110015. Unpublished study prepared by Wildlife International, Ltd. 41 p.	45422418	Sumitomo Chemical Company, Ltd	EXC	
71-2	Johnson, A. (1998) TI-435 Technical Dietary LC50 to the Bobwhite Quail: Lab Project Number: TDA 233: 110050. Unpublished study prepared by Huntingdon Life Sciences Ltd. 45 p.	45422419	Sumitomo Chemical Company, Ltd	EXC	



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Product: CLOTHIANIDIN TECHNICAL

Ingredient: CLOTHIANIDIN

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
71-2	Johnson, A. (1998) TI-435 Technical Dietary LC50 to the Mallard Duck: Lab Project Number: TDA 234: 110051. Unpublished study prepared by Huntingdon Life Sciences Ltd. 41 p.	45422420	Sumitomo Chemical Company, Ltd	EXC	
71-4	TI-435 TECHNICAL: A REPRODUCTION STUDY WITH THE NORTHERN BOBWHITE (COLINUS VIRGINIANUS).	45422421	Sumitomo Chemical Company, Ltd	EXC	
71-4	TI-435 TECHNICAL A REPRODUCTION STUDY WITH THE MALLARD (ANAS PLATYRHYNCHOS).	45422422	Sumitomo Chemical Company, Ltd	EXC	
141-1	TI-435 technical: Acute Contact and Oral Toxicity to Honeybees	45422426	Sumitomo Chemical Company, Ltd	EXC	
None	TI-435 Metabolite TMG: Acute Oral Toxicity to Honey Bees (Apis mellifera)	45422427	Sumitomo Chemical Company, Ltd	EXC	
None	TI-435 Metabolite MNG: Acute Oral Toxicity to Honey Bees (Apis mellifera)	45422428	Sumitomo Chemical Company, Ltd	EXC	
None	TI-435 Metabolite TZMU: Acute Oral Toxicity to Honey Bees (Apis mellifera)	45422429	Sumitomo Chemical Company, Ltd	EXC	
None	TI-435 Metabolite TZNG: Acute Oral Toxicity to Honey Bees (Apis mellifera)	45422430	Sumitomo Chemical Company, Ltd	EXC	



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Ingredient: CLOTHIANIDIN

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
850.4100 850.4225	TI-435 50% WDG: A Toxicity Test To Determine The Effects Of The Test Substance On Seedling Emergence Of Ten Species Of Plants	45422501	Sumitomo Chemical Company, Ltd	EXC	
850.4150	TI-435 50% WDG: A Toxicity Test To Determine The Effects Of The Test Substance On Vegetative Vigor Of Ten Species Of Plants	45422502	Sumitomo Chemical Company, Ltd	EXC	
850.5400	TI-435 Technical: a 5-Day Toxicity Test with the Freshwater Alga, <i>Selenastrum capricornutum</i>	45422504	Sumitomo Chemical Company, Ltd	EXC	
None	Influence of TI-435 Technical on Development and Emergence of Larvae of <i>Chironomus riparius</i> in a Water-Sediment System	45422509	Sumitomo Chemical Company, Ltd	EXC	
None	Influence of TMG (tech.) on Development and Emergence of Larvae of <i>Chironomus riparius</i> in a Water-Sediment System	45422510	Sumitomo Chemical Company, Ltd	EXC	
None	Weyman, G. (1998) TI-435 Technical: Acute Toxicity to the Earthworm <i>Eisenia foetida</i> : Lab Project Number: 586/136: 110067. Unpublished study prepared by Covance Laboratories, Ltd. 27 p.	45422511	Sumitomo Chemical Company, Ltd	EXC	
None	Noack, M. (2000) MNG: Earthworm ( <i>Eisenia foetida</i> ), Acute Toxicity in Artificial Soil: Lab Project Number: 110172: RRA66531/990813TU. Unpublished study prepared by Dr. U. Noack Laboratory for Applied Biology. 34 p.	45422512	Sumitomo Chemical Company, Ltd	EXC	



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CLOTHIANIDIN TECHNICAL

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Date: JUNE 09, 2011	EPA Reg No./ File Symbol: 59639-173	Total Pages = 141
Applicant's/Registrant's Name & Address VALENT U.S.A. CORPORATION 1600 Riviera Avenue, Suite 200 Walnut Creek, CA 94596		Product: CLOTHIANIDIN TECHNICAL

Ingredient: CLOTHIANIDIN

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
None	Noack, M. (2000) TZNG: Earthworm ( <i>Eisenia foetida</i> ), Acute Toxicity in Artificial Soil: Lab Project Number: RRA66521/990813TU: 110280. Unpublished study prepared by Dr. U. Noack Laboratory for Applied Biology.36 p.	45422513	Sumitomo Chemical Company, Ltd	EXC	
None	Analytical Method Verification for the Determination of TI-435 Technical in Avian Diet	45422514	Sumitomo Chemical Company, Ltd	EXC	
860.1300	Metabolism of TI-435 in Corn	45422527	Sumitomo Chemical Company, Ltd	EXC	
860.1300	Metabolism of [Thiazolyl-2-14C]TI-435 in Corn (Second-Label Study)	45422528	Sumitomo Chemical Company, Ltd	EXC	
860.1300	[Nitroimino-14C] TI-435 Sugar Beet Metabolism Seed Treatment	45422529	Sumitomo Chemical Company, Ltd	EXC	
860.1300	Metabolism of T-435 in Tomatoes Using a GR Formulation	45422530	Sumitomo Chemical Company, Ltd	EXC	
860.1300	Metabolism of TI-435 in Tomatoes Using an SC Formulation	45422531	Sumitomo Chemical Company, Ltd	EXC	
860.1300	Metabolism of TI-435 in Apples Part 1 of 2: Apple Fruits	45422532	Sumitomo Chemical Company, Ltd	EXC	
860.1300	Metabolism of TI-435 in Apples Part 2 of 2: Apple Leaves	45422533	Sumitomo Chemical Company, Ltd	EXC	



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CLOTHIANIDIN TECHNICAL

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Product: CLOTHIANIDIN TECHNICAL

Ingredient: CLOTHIANIDIN

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
860.1300	[Nitroimino-14C] TI-435 Absorption, Distribution, Excretion, and Metabolism in the Lactating Goat	45422534	Sumitomo Chemical Company, Ltd	EXC	
860.1300	[Nitroimino-14C] TI-435 Investigation of Metabolites in Tissues and Eggs of Laying Hen	45422535	Sumitomo Chemical Company, Ltd	EXC	
860.1480	TI-435 - Dairy Cattle Feeding Study	45422613	Sumitomo Chemical Company, Ltd	EXC	
860.1850	Confined Rotational Crop Study with TI-435	45422618	Sumitomo Chemical Company, Ltd	EXC	
870.1100	TI-435: Acute Oral Toxicity Study in the Rat	45422621	Sumitomo Chemical Company, Ltd	EXC	
870.1100	TI-435: Acute Oral Toxicity Study in the Mouse	45422622	Sumitomo Chemical Company, Ltd	EXC	
870.1100	BN0335E2: Acute Oral Toxicity Study in the Rat	45422623	Sumitomo Chemical Company, Ltd	EXC	
870.1100	TZMU: Acute Oral Toxicity Study in the Rat	45422624	Sumitomo Chemical Company, Ltd	EXC	
870.1100	Methyl Guanidine (MG): Acute Oral Toxicity Study in the Rat	45422625	Sumitomo Chemical Company, Ltd	EXC	
870.1100	TZNG: Acute Oral Toxicity Study in the Rat	45422626	Sumitomo Chemical Company, Ltd	EXC	



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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.1100	TMG: Acute Oral Toxicity Study in the Rat	45422627	Sumitomo Chemical Company, Ltd	EXC	
870.1100	BN0230M: Acute Oral Toxicity Study in the Rat	45422628	Sumitomo Chemical Company, Ltd	EXC	
870.1100	MAI: Acute Oral Toxicity Study in the Rat	45422629	Sumitomo Chemical Company, Ltd	EXC	
870.1200	TI-435: Acute Dermal Toxicity Study in the Rat	45422634	Sumitomo Chemical Company, Ltd	EXC	
870.1300	TI-435: Single Dose Inhalation (Head-Only) Toxicity Study in the Rat	45422636	Sumitomo Chemical Company, Ltd	EXC	
870.2400	TI-435: Acute Eye Irritation Study in Rabbits	45422701	Sumitomo Chemical Company, Ltd	EXC	
870.2500	TI-435: Skin Irritation Study in Rabbits	45422703	Sumitomo Chemical Company, Ltd	EXC	
870.2600	TI-435: Skin Sensitization Study in Guinea Pig	45422705	Sumitomo Chemical Company, Ltd	EXC	
870.3200	28-Day Dermal Toxicity Study with TI-435 in Rats	45422707	Sumitomo Chemical Company, Ltd	EXC	
None	TI-435: Toxicity to Rats by Dietary Administration for 4 Weeks	45422708	Sumitomo Chemical Company, Ltd	EXC	



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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
None	TI-435: Toxicity to Mice by Dietary Administration for 4 Weeks	45422709	Sumitomo Chemical Company, Ltd	EXC	
870.3700	Oral (Gavage) Dose-Range Developmental Toxicity Study of TI-435 in Rats	45422710	Sumitomo Chemical Company, Ltd	EXC	
870.3700	Oral (Gavage) Developmental Toxicity Study of TI-435 in Rats	45422711	Sumitomo Chemical Company, Ltd	EXC	
870.3700	Oral (Stomach Tube) Developmental Toxicity Study of TI-435 in Rabbits	45422712	Sumitomo Chemical Company, Ltd	EXC	
870.3700	Oral (Stomach Tube) Developmental Toxicity Study of TI-435 in Rabbits	45422713	Sumitomo Chemical Company, Ltd	EXC	
83-4	A Pilot Reproductive Toxicity Study with TI-435 in the Sprague-Dawley Rat	45422714	Sumitomo Chemical Company, Ltd	EXC	
870.3800	A Two Generation Reproductive Toxicity Study with TI-435 in the Sprague-Dawley Rat	45422715	Sumitomo Chemical Company, Ltd	EXC	
870.3800	A Two Generation Reproductive Toxicity Study with TI-435 in the Sprague-Dawley Rat; Supplemental Submission	45422716	Sumitomo Chemical Company, Ltd	EXC	
870.4100	52-Week Dietary Chronic Toxicity Study with TI-435 in Dogs	45422717	Sumitomo Chemical Company, Ltd	EXC	
870.4100	52-Week Dietary Chronic Toxicity Study with TI-435 in Dogs; Supplemental Submission	45422718	Sumitomo Chemical Company, Ltd	EXC	



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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.4300	104-Week Dietary Combined Chronic Toxicity and Carcinogenicity Study with TI-435 in Rats	45422719	Sumitomo Chemical Company, Ltd	EXC	
870.4300	104-Week Dietary Combined Chronic Toxicity and Carcinogenicity Study with TI-435 in Rats	45422720	Sumitomo Chemical Company, Ltd	EXC	
870.4200	78-Week Dietary Carcogenicity Study with TI-435 in Mice	45422721	Sumitomo Chemical Company, Ltd	EXC	
870.4200	78-Week Dietary Carcogenicity Study with TI-435 in Mice; Supplemental Submission	45422722	Sumitomo Chemical Company, Ltd	EXC	
None	Analytical Validation and Stability of TI 435 in Rodent Chow	45422723	Sumitomo Chemical Company, Ltd	EXC	
870.5265	BN0335E2: Reverse Mutation in Five Histidine-Requiring Strains of Salmonella typhimurium	45422724	Sumitomo Chemical Company, Ltd	EXC	
870.5265	TZMU: Reverse Mutation in Five Histidine-Requiring Strains of Salmonella typhimurium	45422725	Sumitomo Chemical Company, Ltd	EXC	
870.5265	Methyl Guanidine: Reverse Mutation in Five Histidine-Requiring Strains of Salmonella typhimurium	45422726	Sumitomo Chemical Company, Ltd	EXC	
870.5265	TZNG: Reverse Mutation in Five Histidine-Requiring Strains of Salmonella typhimurium	45422727	Sumitomo Chemical Company, Ltd	EXC	
870.5265	TMG: Reverse Mutation in Five Histidine-Requiring Strains of Salmonella typhimurium	45422728	Sumitomo Chemical Company, Ltd	EXC	



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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.5265	BN0230M: Reverse Mutation in Five Histidine-Requiring Strains of Salmonella typhimurium	45422729	Sumitomo Chemical Company, Ltd	EXC	
870.5265	MAI: Reverse Mutation in Five Histidine-Requiring Strains of Salmonella typhimurium	45422730	Sumitomo Chemical Company, Ltd	EXC	
870.5100	TI-435: Reverse Mutation Assay "Ames Test" Using Salmonella typhimurium and Escherchia coli	45422731	Sumitomo Chemical Company, Ltd	EXC	
870.5100	Bacterial Reverse Mutation Test of TIR-435	45422732	Sumitomo Chemical Company, Ltd	EXC	
870.5100	TI-435: Salmonella/Microsome Test Plate Incorporation and Preincubation Method	45422733	Sumitomo Chemical Company, Ltd	EXC	
870.5100	TI-435: Salmonella/Microsome Test Using Salmonella Typhimurium TA 1535 Plate Incorporation and Preincubation Method	45422734	Sumitomo Chemical Company, Ltd	EXC	
870.5500	DNA Repair Test of TIR-435 in Bacillus subtilis	45422735	Sumitomo Chemical Company, Ltd	EXC	
870.5100	TI-435: Chromosome Aberration Test in CHL Cells in Vitro	45422736	Sumitomo Chemical Company, Ltd	EXC	
870.5300	L5178Y TK +/- Mouse Lymphoma Assay	45422737	Sumitomo Chemical Company, Ltd	EXC	



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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.5300	TI-435: Mutagenicity Study for the Detection of Induced Forward Mutations in the V79-HPRT Assay in Vitro	45422738	Sumitomo Chemical Company, Ltd	EXC	
870.5500	TI-435: Test on Unscheduled DNA Synthesis with Rat Liver Cells in Vivo	45422739	Sumitomo Chemical Company, Ltd	EXC	
870.5395	TI-435: Micronucleus Test in the Mouse	45422740	Sumitomo Chemical Company, Ltd	EXC	
870.6200	An Acute Oral Neurotoxicity Screening Study with Technical Grade TI-435 in Fischer 344 Rats	45422801	Sumitomo Chemical Company, Ltd	EXC	
870.6200	An Acute Oral Neurotoxicity Screening Study with Technical Grade TI-435 in Fischer 344 Rats; Supplemental Submission # 1	45422802	Sumitomo Chemical Company, Ltd	EXC	
870.6200	A Subchronic Neurotoxicity Screening Study with Technical Grade TI-435 in Fischer 344 Rats	45422803	Sumitomo Chemical Company, Ltd	EXC	
870.6300	Hoberman, A. (2000) Developmental Neurotoxicity Study of TI 435 Administered Orally via Diet to CRL: CD Presumed Pregnant Rats: Lab Project Number: 110218: ARGUS 1120-003: 1120-003. Unpublished study prepared by Argus Research Laboratories, Inc. 1421 p.	45422804	Sumitomo Chemical Company, Ltd	EXC	
870.7485	[Nitroimino-14C] TI-435 Toxicokinetic Behaviour and Metabolism in the Rat Including Whole Body Autoradiography	45422805	Sumitomo Chemical Company, Ltd	EXC	



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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
None	Determination of Metabolites of TI-435 in Major Tissues of Rats	45422806	Sumitomo Chemical Company, Ltd	EXC	
870.7485	Absorption, Distribution, Metabolism and Excretion of TI-435 in Mice	45422807	Sumitomo Chemical Company, Ltd	EXC	
None	4-Week Dietary Toxicity Study with TI-435 in Dogs	45422808	Sumitomo Chemical Company, Ltd	EXC	
82-1	Technical Grade TI-435: A Subchronic Toxicity Testing Study in the Rat	45422809	Sumitomo Chemical Company, Ltd	EXC	
870.3150	13-Week Dietary Toxicity Study with TI-435 in Dogs	45422810	Sumitomo Chemical Company, Ltd	EXC	
None	Palatability Pilot Study for Dietary Concentrations of TI-435 in Dogs	45422811	Sumitomo Chemical Company, Ltd	EXC	
None	Pharmacological Studies on TI-435	45422823	Sumitomo Chemical Company, Ltd	EXC	
None	TI-435: Position Paper on Studies Conducted at Huntingdon Life Sciences, U.K. / discussion of why studies conducted at HLS will not be included in the toxicology data package for registration purposes	45422824	Sumitomo Chemical Company, Ltd	EXC	
None	The Homogeneity, Room Temperature and Freezer Stability of TI-435 in Rodent Ration	45422825	Sumitomo Chemical Company, Ltd	EXC	



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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
None	The Homogeneity, Room Temperature and Freezer Stability of TI-435 in Rodent Ration	45422826	Sumitomo Chemical Company, Ltd	EXC	
None	A Liquid Chromatographic Method for the Determination of TI-435 in Dose Preparations	45422827	Sumitomo Chemical Company, Ltd	EXC	
None	A Liquid Chromatographic Method for the Determination of TI-435 in Rodent Ration	45422828	Sumitomo Chemical Company, Ltd	EXC	
830.1550	Fontaine, L. (2001) Product Chemistry of Clothianidin Technical: Lab Project Number: BR 2098. Unpublished study prepared by Bayer Corp. 6 p.	45569801	Sumitomo Chemical Company, Ltd	EXC	
830.1550 830.1670 830.1750	Fontaine, L. (2002) Supplemental Product Chemistry of Clothianidin Technical: Lab Project Number: BR 2210. Unpublished study prepared by Bayer Corp. 429 p.	45654601	Sumitomo Chemical Company, Ltd	EXC	
870.5300	Poth, A. (2003) Gene Mutation Assay in Chinese Hamster V79 Cells in Vitro (V79/HPRT) with TI-435. Project Number: 802501, TI/435. Unpublished study prepared by RCC Umweltchemie GmbH & Co. Kg. 39 p.	46339001	Sumitomo Chemical Company, Ltd	EXC	



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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.5375	Schulz, M. (2003) In Vitro Chromosome Aberration Test In Chinese Hamster V79 Cells with TI-435. Project Number: 802502, TI/435. Unpublished study prepared by RCC Umweltchemie Gmbh & Co. Kg. 33 p.	46339002	Sumitomo Chemical Company, Ltd	EXC	
870.5395	Honarvar, N. (2003) TI-435 Micronucleus Assay in Bone Marrow Cells of the Mouse. Project Number: 802503, TI/435. Unpublished study prepared by RCC Umweltchemie Gmbh & Co. Kg. 26 p.	46339003	Sumitomo Chemical Company, Ltd	EXC	
OECD 486	Honarvar, N. (2003) In Vivo/In Vitro Unscheduled DNA Synthesis in Rat Hepatocytes with TI-435. Project Number: 802504, TI/435. Unpublished study prepared by RCC Umweltchemie Gmbh & Co. Kg. 27 p.	46339004	Sumitomo Chemical Company, Ltd	EXC	
870.4300	Beigel, L. (2004) 104-Week Dietary Combined Chronic Toxicity and Carcinogenicity Study with TI-435 in Rats (Supplement No. 2): Supplement to Final Study. Project Number: 6155/108. Unpublished study prepared by Covance Laboratories, Inc. 114 p.	46339010	Sumitomo Chemical Company, Ltd	EXC	



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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.7800	Hoberman, A. (2004) Oral (Diet) Repeated Dose 28-Day Toxicity/Immunotoxicity Study of TI-435 in Rats: Final Report. Project Number: RLF00001. Unpublished study prepared by Charles River Laboratories and ImmunoTox, Inc. 187 p.	46536502	Sumitomo Chemical Company, Ltd	EXC	
850.1735	Putt, A. (2006) Clothianidin - Toxicity to Midge (Chironomus riparius) During a 10-Day Sediment Exposure. Project Number: EBTIX063, 13798/6182. Unpublished study prepared by Springborn Smithers Laboratories. 58 p.	46826902	Sumitomo Chemical Company, Ltd	EXC	
	Ripperger, R. (2006) [Thiazolyl-2-(Carbon 14)]-Clothianidin: Aerobic Aquatic Metabolism. Project Number: METIX052, 05METIX052. Unpublished study prepared by Sumitomo Chemical Takeda Agro Co., Ltd. 79 p.	46826903	Sumitomo Chemical Company, Ltd	EXC	
830.1700	Preliminary Analysis of Clothianidin Technical Grade Active Ingredient	47278101	Sumitomo Chemical Company, Ltd	EXC	
860.1500	Dorschner, K. (2007) Clothianidin: Magnitude of the Residue on Peach. Project Number: 08544/04/BER01, 08544, 08544/04/NJ23. Unpublished study prepared by Interregional Research Project No. 4, Cornell University, and Rutgers Agricultural Research and Extension Center. 247 p.	47578101	IR-4	PL	



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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
860.1500	Dorschner, K. (2008) Clothianidin: Magnitude of the Residue on Peach. Project Number: A8544/06/NC28, A8544/06/BER07, A8544. Unpublished study prepared by Interregional Research Project No. 4, U.S. Dept. of Agriculture and IR-4 SE Region Analytical Lab. 97 p.	47578102	IR-4	PL	
860.1500	Corley, J. (2008) Clothianidin: Magnitude of the Residue on Cranberry: Final Report. Project Number: 09399, 09399/05/MIR14, 09399/05/MA01. Unpublished study prepared by Interregional Research Project No. 4, IR-4 North Central Analytical Lab and Cranberry Experiment Station. 160 p.	47578103	IR-4	PL	
860.1340	Enforcement Method 00657 for the Determination of the Residues of TI-435 in Plant Material	45422305	Bayer CropScience	EXC	
860.1340	Enforcement Method 00656 for the Determination of the Residues of TI-435 In Animal Matrices	45422306	Bayer CropScience	EXC	
None	Partition Coefficient in Octanol-Water of TI 435-TZNG	45422307	Bayer CropScience	EXC	
None	Partition Coefficient in Octanol-Water of TI 435-MNG	45422308	Bayer CropScience	EXC	
None	Partition Coefficient in Octanol-Water of TI 435-TZMU	45422309	Bayer CropScience	EXC	



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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
None	Partition Coefficient in Octanol-Water of TI 435-TMG	45422310	Bayer CropScience	EXC	
162-4	[14C]TI-435: Aerobic Aquatic Biotransformation	45422329	Bayer CropScience	EXC	
164-1	Degradation and Translocation Behavior of the Insecticide TI-435 Under Field Conditions in a Lysimeter (Autumn Application)	45422331	Bayer CropScience	EXC	
164-1	TI-435 - Terrestrial Field Dissipation Study, Wisconsin, 1998	45422332	Bayer CropScience	EXC	
164-1	TI-435 - Terrestrial Field Dissipation Study, Ohio, 1998	45422333	Bayer CropScience	EXC	
164-1	TI-435 - Terrestrial Field Dissipation Study, North Dakota, 1998	45422334	Bayer CropScience	EXC	
164-1	TI-435 - Terrestrial Field Dissipation Study, Ontario, Canada, 1998	45422335	Bayer CropScience	EXC	
164-1	TI-435 - Terrestrial Field Dissipation Study, Saskatchewan, Canada, 1998	45422336	Bayer CropScience	EXC	
166-1	Enforcement Method 00659 for the Determination of the Residues of TI-435 in Drinking and Surface Water	45422337	Bayer CropScience	EXC	



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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
850.1010	TI-435 Technical: A 48-Hour Static Acute Toxicity Test with the Cladoceran ( <i>Daphnia magna</i> )	45422338	Bayer CropScience	EXC	
72-2	Acute Toxicity of TI-435-Thiazolylmethylguanidine (techn.) to Water Fleas ( <i>Daphnia magna</i> )	45422339	Bayer CropScience	EXC	
72-2	Acute Toxicity of N-Methylnitroguanidine (techn.) to Water Fleas ( <i>Daphnia magna</i> )	45422340	Bayer CropScience	EXC	
72-2	Acute Toxicity of TI-435-Thiazolylnitroguanidine (techn.) to Water Fleas ( <i>Daphnia magna</i> )	45422401	Bayer CropScience	EXC	
None	Acute Toxicity of Leachate Water Samples of a Lysimeter Study on TI-435 (Lysimeter 17 and 18, sampling time: 1999-10-11 to 2000-07-07) to Water Fleas	45422402	Bayer CropScience	EXC	
72-1	TI-435 Technical: A 96-Hour Static Acute Toxicity Test with the Bluegill ( <i>Lepomis macrochirus</i> )	45422407	Bayer CropScience	EXC	
850.1075	TI 435 - ThiazolylMethylnitroguanidine - Acute Toxicity (96 hours) to Rainbow Trout ( <i>Oncorhynchus mykiss</i> ) in a Static Test (Limit Test)	45422408	Bayer CropScience	EXC	
72-1	N-Methylnitroguanidine - Acute Toxicity (96 hours) to Rainbow Trout ( <i>Oncorhynchus mykiss</i> ) in a Static Test (Limit Test)	45422409	Bayer CropScience	EXC	



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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
850.1075 (72-1)	TI-435 - Thiazolynitroguanidine - Acute Toxicity (96 hours) to Rainbow Trout ( <i>Oncorhynchus mykiss</i> ) in a Static Test (Limit Test)	45422410	Bayer CropScience	EXC	
850.1400	TI-435 Technical: An Early Life-Stage Toxicity Test with Fathead Minnow ( <i>Pimephales promelas</i> )	45422413	Bayer CropScience	EXC	
None	Acute Toxicity of Leachate Water Samples of a Lysimeter Study on TI-435 (Lysimeter 17, 18, and 24, sampling time May 1999) to <i>Chironomus riparius</i>	45422415	Bayer CropScience	EXC	
None	Acute Toxicity of Leachate Water Samples of a Lysimeter Study on TI-435 (Year Sample of Lysimeter 17 and 18 from the 3rd Test Year) to <i>Chironomus riparius</i>	45422416	Bayer CropScience	EXC	
None	Barfknecht, R. (2001) Attractiveness of Freshly Drilled Maize Fields for Large seed Eating Birds (TI-435 Technical): Lab Project Number: E308 1831-4: 110400. Unpublished study prepared by Bayer AG. 35 p.	45422423	Bayer CropScience	EXC	
None	Wolf, C. (2001) Generic Avian Field Study on Freshly Drilled Oiled Rape Fields in Great Britain (TI-435 Technical): Lab Project Number: E308 1918-0: 110293. Unpublished study prepared by Bayer AG. 125 p.	45422424	Bayer CropScience	EXC	



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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
None	TI-435: Residue Levels in Corn Seeds and Seedlings	45422425	Bayer CropScience	EXC	
None	Residues of TI 435 in Nectar, Blossoms, Pollen and Honey Bees Sampled from a Summer Rape Field in Sweden and Effects of These Residues on Foraging Honeybees	45422431	Bayer CropScience	EXC	
None	Residues of TI 435 in Nectar, Blossoms, Pollen and Honey Bees Sampled from a British Summer Rape Field and Effects of These Residues on Foraging Honeybees	45422432	Bayer CropScience	EXC	
None	Residues of TI 435 in Nectar, Blossoms, Pollen and Honey Bees Sampled from a French Summer Rape Field and Effects of These Residues on Foraging Honeybees	45422433	Bayer CropScience	EXC	
None	Effects of Diet (Sugar Solution) Spiked with TI-435 Technical on Behavior and Mortality of Honey Bees (Apis mellifera) and on the Weight Development of Bee Colonies Under Field Conditions	45422434	Bayer CropScience	EXC	



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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
None	Scott-Dupree, C.; Spivak, M.; Bruns, G. et al. (2001) The Impact of GAUCHO and TI-435 Seed-Treated Canola on Honey Bees, Apis mellifera L: Lab Project Number: 110403. Unpublished study prepared by University of Guelph, University of Minnesota, and Enviro-Test Laboratories. 131 p.	45422435	Bayer CropScience	EXC	
None	Residue Levels of TI-435 FS 600 and its Relevant Metabolites in Nectar, Blossoms and Pollen of Summer Rape from Dressed Seeds and Effects of These Residues on Foraging Honeybees (Test Location: Farmland "Laacher Hof")	45422436	Bayer CropScience	EXC	
None	Residue Levels of TI-435 FS 600 and its Relevant Metabolites in Nectar, Blossoms and Pollen of Summer Rape from Dressed Seeds and Effects of These Residues on Foraging Honeybees (Test Location: Farmland "Hofchen")	45422437	Bayer CropScience	EXC	
None	Residue Levels of TI-435 FS 600 and its Relevant Metabolites in Pollen of Maize Plants from Dressed Seeds (Test Location: Farmland "Laacher Hof")	45422438	Bayer CropScience	EXC	
None	Residue Levels of TI-435 FS 600 and its Relevant Metabolites in Pollen of Maize Plants from Dressed Seeds (Test Location: Farmland Hofchen)	45422439	Bayer CropScience	EXC	



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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
None	Effects of TI-435 Residues in Pollen on the Development of Small Bee Colonies and on Behavior and Mortality of Honey Bees	45422440	Bayer CropScience	EXC	
850.4400	TI-435 Technical: A 14-Day Static-Renewal Toxicity Test with Duckweed ( <i>Lemna gibba</i> G3)	45422503	Bayer CropScience	EXC	
850.5400	TI-435 - Thiazolylmethylguanidine - Influence on the Growth of Green Alga, <i>Selenastrum capricornutum</i>	45422505	Bayer CropScience	EXC	
850.5400	N-Methylnitroguanidine - Influence on the Growth of Green Alga, <i>Selenastrum capricornutum</i>	45422506	Bayer CropScience	EXC	
850.5400	TI-435 - Thiazolylnitroguanidine - Influence on the Growth of Green Alga, <i>Selenastrum capricornutum</i>	45422507	Bayer CropScience	EXC	
164-1	Degradation and Translocation Behavior of the Insecticide TI-435 in a Lysimeter Under Field Conditions	45422508	Bayer CropScience	EXC	
None	Barfknecht, R. (1998) Acceptance of TI 435 FS 600-Coated Rape Seeds (1.67 L product/100 kg seed) by Japanese Quail ( <i>Coturnix coturnix japonica</i> ): Lab Project Number: E200 1349-9: 110178. Unpublished study prepared by Bayer AG. 34 p.	45422515	Bayer CropScience	EXC	



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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
None	Barfknecht, R. (1998) Acceptance of TI 435 FS 600-Coating of Maize Seeds (50 g a.i./5000 seeds) by Domestic Pigeon (Columba livia-f. domestica) according to BBA-Test Guideline 25-1: Lab Project Number: E 200 1351-2: 110070. Unpublished study prepared by Bayer AG. 28 p.	45422516	Bayer CropScience	EXC	
None	Barfknecht, R. (2000) Acceptance of TI 435 FS 600 (25 g a.i./unit) Treated Seeds by Domestic Pigeon (Columba livia f. domestica): Lab Project Number: E200 1922-6: 110181. Unpublished study prepared by Bayer AG.22 p.	45422517	Bayer CropScience	EXC	
None	Kemmeter, F. (1999) TI-435 FS 600 (Treated Corn Seeds): Extended Laboratory Study to Evaluate the Effects on the Lycosid Spider, Pardosa spp. (Araneae, Lycosidae): Lab Project Number: 99089/01-NEPA: 110176. Unpublished study prepared by Arbeitsgemeinschaft. 49 p.	45422518	Bayer CropScience	EXC	
None	Kemmeter, F. (1999) Clothianidin (FS 600) (Treated Rape Seeds): Extended Laboratory Study to Evaluate the Effects on the Wolf Spider, Pardosa spp. (Araneae, Lycosidae): Lab Project Number: 99085 01-NEPa: 110175. Unpublished study prepared by Arbeitsgemeinschaft GAB Biotechnologie GmbH & IFU Umweltanalytik GmbH. 44 p.	45422519	Bayer CropScience	EXC	



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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
None	Schmuck, R. (2000) Acute Effects of Maize Seed Treated with TI 435 FS 600 on Carabid Beetles ( <i>Poecilus cupreus</i> ) Under Extended Laboratory Test Conditions: Lab Project Number: E 371 1410-7: 110047. Unpublished study prepared by Bayer AG. 24 p.	45422520	Bayer CropScience	EXC	
None	Schmuck, R. (2000) Acute Effects of Summerrape Seed Treated with TI 435 FS 600 on Carabid Beetles ( <i>Poecilus cupreus</i> ) Under Extended Laboratory Test Conditions: Lab Project Number: E 371 1377-9: 110069. Unpublished study prepared by Bayer AG. 24p.	45422521	Bayer CropScience	EXC	
None	Schmuck, R. (2000) Effects of Maize Seed Dressed with TI 435 FS 600 on the Life Cycle of Rove Beetles ( <i>Aleochara bilineata</i> ) Under Extended Laboratory Test Conditions: Lab Project Number: E 380 1399-3: 110061. Unpublished study prepared by Bayer AG. 24p.	45422522	Bayer CropScience	EXC	
None	Schmuck, R. (2000) Effects of Summer Rape Seed Coated with TI 435 FS 600 on the Life Cycle of Rove Beetles ( <i>Aleochara bilineata</i> ) Under Extended Laboratory Test Conditions: Lab Project Number: E 380-1390-4: 110062. Unpublished study prepared by Bayer AG. 24p.	45422523	Bayer CropScience	EXC	



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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
None	Effects of TI-435 a.i. on the Life Cycle of Rove Beetles ( <i>Aleochara bilineata</i> ) Under Extended Laboratory Conditions	45422524	Bayer CropScience	EXC	
None	Meisner, P. (2000) Influence of TI-435 600 FS Dressed Corn on the Reproduction of Earthworms ( <i>Eisenia fetida</i> ): Lab Project Number: E 312 1817-3: 110068. Unpublished study prepared by Bayer AG. 21p.	45422525	Bayer CropScience	EXC	
None	Heimbach, F. (2000) Effect of TI-435 600 FS Dressed Corn on the Earthworm Fauna of an Arabia Field: Lab Project Number: E311 1607-9: 110180. Unpublished study prepared by Bayer AG. 82 p.	45422526	Bayer CropScience	EXC	
860.1340	Residue Analytical Method 00552 for the Determination of TI 435 in Plant Materials by LC-MS/MS	45422536	Bayer CropScience	EXC	
860.1340	Modification M001 of the Method 00552 for the Determination of TI 435 in/on Plant Materials	45422537	Bayer CropScience	EXC	
860.1340	Additional Validation Data for the Analytical Residue Analytical Method for the Detection of TI 435 in Crop Matrices	45422538	Bayer CropScience	EXC	
860.1340	Independent Laboratory Validation of Analytical Method 109240 Residue Analytical Method 00552 for the Determination of TI 435 in Plant Materials by LC-MS/MS	45422539	Bayer CropScience	EXC	



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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
860.1340	Extraction Efficiency Testing of the Residue Method for the Determination of TI-435 Residues in Corn and in Apple Using Aged Radioactive Residues	45422540	Bayer CropScience	EXC	
164-1	Residue Analytical Method 00521 (MR-343/98) for Determination of TI-435 and the Metabolites TZNG, TZMU, MNG and TMG in Soil by Liquid Chromatography with Electrospray MS/MS-Detection	45422601	Bayer CropScience	EXC	
164-1	Analytical Method for the Determination of TI-435 and the Degradates, TZNG, TZMU, MNG and TMG in Soil by Liquid Chromatography wiht APCI MS/MS- Detection	45422602	Bayer CropScience	EXC	
164-1	Independent Laboratory Validation of Bayer Report Number 110263 for the Determination of TI-435 and the Degradates TZNG, TZMU, MNG and TMG, in Soil by High-Performance Liquid Chromatography Tandem Mass Spectrometry (HPLC/MS-MS)	45422603	Bayer CropScience	EXC	
164-1	Radiovalidation of the TI-435 Soil Residue Analytical Method	45422604	Bayer CropScience	EXC	



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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
164-1	Independent Laboratory Validation of Bayer Report Number 109586 for the Determination of TI-435 and the Degradates TZNG, TZMU, MNG and TMG, in Soil by High-Performance Liquid Chromatography Tandem Mass Spectrometry (HPLC/MS-MS)	45422605	Bayer CropScience	EXC	
860.1340	Validation of the Residue Analytical Method 00624 for the Determination of TI-435, TZG, TZU, and PTMG (Pyruvate) in Animal Materials by HPLC-MS/MS	45422606	Bayer CropScience	EXC	
860.1340	Additional Validation Data for the Analytical Residue Method for the Determination of TI-435, TZG, TZU, and PTMG Residues in Animal Matrices	45422607	Bayer CropScience	EXC	
860.1340	Independent Laboratory Validation of TI-435 Animal Method Entitled, "Validation of the Residue Analytical Method 00624 for the Determination of TI- 435, TZG, TZU, and PTMG (pyruvate) in Animal Materials by HPLC-MS/MS	45422608	Bayer CropScience	EXC	
860.1340	Extraction Efficiency Testing of the Residue Method for the Determination of TI-435 Residues in Animal Using Aged Radioactive Residues	45422609	Bayer CropScience	EXC	



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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
860.1360	Multiresidue Method Testing for TI-435, MNG, ATMG-Pyr, TZG, TZNG, and TZU According to PAM I, Appendix II as Updated Jan 1994	45422610	Bayer CropScience	EXC	
860.1380	Determination of the Storage Stability of TI-435 Residues in Fortified Analytical Samples of Plant Materials	45422611	Bayer CropScience	EXC	
164-1	Determination of the Storage Stability of TI-435 and of the Metabolites TZNG, TZMU, TMG and MNG in Soil - Interim Report	45422612	Bayer CropScience	EXC	
860.1500	TI-435 600 FS - Magnitude of the Residue in Field, Pop, and Sweet Corn	45422614	Bayer CropScience	EXC	
860.1500	TI-435 600 FS - Magnitude of the Residue in Canola	45422615	Bayer CropScience	EXC	
860.1500	Determination of Residues of TI-435 (clothianidin) Residues in Canola Following Application of TI-435 600 FS as a Seed Dressing Forbes, NSW.2000	45422616	Bayer CropScience	EXC	
860.1500	Determination of Residues of TI-435 600 FS in Pinnacle Canola Naracoorte, SA. 200	45422617	Bayer CropScience	EXC	
860.1900	TI-435 600 FS- Magnitude of the Residue in Field Rotational Crops	45422619	Bayer CropScience	EXC	



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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
860.1900	TI-435 600 FS - Magnitude of the Residue in Field Rotational Crops; Addendum 1; Magnitude of the Residue of TZN	45422620	Bayer CropScience	EXC	
870.1100	Krotlinger, F. (2000) TI 435-CCMT-AADUCT Study for Acute Oral Toxicity Study in Rats: Lab Project Number: PH 29814: T2069070: 110213. Unpublished study prepared by Bayer AG. 29 p.	45422630	Bayer CropScience	EXC	
870.1100	Krotlinger, F. (2000) TI 435-Hexahydropyrimidine (By-Product of Technical TI 435) Study for Acute Oral Toxicity Study in Rats: Lab Project Number: PH 30517: T4070025. Unpublished study prepared by Bayer AG. 27 p.	45422631	Bayer CropScience	EXC	
870.1100	Krotlinger, F. (2000) TI 435-Triazan Acute Oral Toxicity Study in Male and Female Wistar Rats: Lab Project Number: PH 30096: T5069640. Unpublished study prepared by Bayer AG. 26 p. {OPPTS 870.1100}	45422632	Bayer CropScience	EXC	
870.5100	N-Methylnitroguanidin Salmonella/Microsome Test Plate Incorporation and Preincubation Method	45422812	Bayer CropScience	EXC	
870.2500	Leuschner, P. (1999) Acute Skin Irritation Test (Patch Test) of TI 435-CCMT-ADDUCT in Rabbits: Lab Project Number: R 7683: T 1067242: 9300/391/95. Unpublished study prepared by LPT Laboratory of Pharmacology and Toxicology. 21 p.	45422813	Bayer CropScience	EXC	



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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.2400	Leuschner, P. (1999) Acute Eye Irritation Study of TI 435-CCMT Adduct by Instillation into the Conjunctival Sac of Rabbits: Lab Project Number: R 7682: T 1067242: 9301/391/95. Unpublished study prepared by LPT Laboratory of Pharmacology and Toxicology. 23 p.	45422814	Bayer CropScience	EXC	
870.2600	Vohr, H. (2000) TI 435-CCMT-ADDUCT Study for the Skin Sensitization Effect in Guinea Pigs (Guinea Pig Maximization Test According to Magnusson and Kligman): Lab Project Number: PH 29817: T 6069272: 110214. Unpublished study prepared by Bayer AG. 29 p.	45422815	Bayer CropScience	EXC	
870.5100	Herbold, B. (2000) TI 435-CCMT-ADDUCT Salmonella/Microsome Test Plate Incorporation and Preincubation Method: Lab Project Number: PH 30144: T 8068860: 110216. Unpublished study prepared by Bayer AG. 51p {OPPTS 870.5100}	45422816	Bayer CropScience	EXC	
870.5100	Herbold, B. (2000) TI 435-Benzyltriazinone Salmonella/Microsome Test Plate Incorporation and Preincubation Method: Lab Project Number: PH 30065: T 6068886: 110215. Unpublished study prepared by Bayer AG. 51p	45422817	Bayer CropScience	EXC	



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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.5100	Herbold, B. (2001) TI 435-Hexahydropyrimidine Salmonella/Microsome Test Plate Incorporation Method: Lab Project Number: PH 30734: T 2069890: 110243. Unpublished study prepared by Bayer Ag. 51 p. {OPPTS 870.5100}	45422818	Bayer CropScience	EXC	
870.2400	Leuschner, P. (2001) Acute Eye Irritation Study of TI 435-TRIAZAN by Instillation into the Conjunctival Sac of Rabbits: Lab Project Number: R 7805: T7069165: 9301/423/95. Unpublished study prepared by LPT Laboratory of Pharmacology and Toxicology. 24 p.	45422819	Bayer CropScience	EXC	
870.2500	Leuschner, P. (2000) Acute Skin Irritation Test (Patch Test) of TI 435-TRIAZAN in Rabbits: Lab Project Number: R 7804: T7069165: 9300/423/95. Unpublished study prepared by LPT Laboratory of Pharmacology and Toxicology. 22 p. {OPPTS 870.2500}	45422820	Bayer CropScience	EXC	
870.2600	Vohr, H. (2000) TI 435-TRIAZAN Study for the Skin Sensitization Effect in Guinea Pigs (Guinea Pig Maximization Test According to Magnusson and Kligman): Lab Project Number: PH-30219: T 9069608: 110217. Unpublished study prepared by Bayer AG. 26 p. {OPPTS 870.2600}	45422821	Bayer CropScience	EXC	



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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.5100	Herbold, B. (2000) TI 435-Triazan Salmonella/Microsome Test Plate Incorporation and Preincubation Method: Lab Project Number: PH 30172; T 4069135; 110241. Unpublished study prepared by Bayer AG. 54p. {OPPTS 870.5100}	45422822	Bayer CropScience	EXC	
870.7600	Sebesta, C. (2003) A Study to Determine the Dermal Absorption of TI 435 FS 600 when Administered Dermal to Male Rhesus Monkeys. 104 p.	45868001	Bayer CropScience	EXC	
	Sokilowski, A. (2003) TI-435 Salmonella Typhimurium Reverse Mutation Assay. Project Number: 803401. Unpublished study prepared by RCC Umweltchemie GmbH & Co. Kg. 35 p.	46339005	Bayer CropScience	EXC	
870.5300	Poth, A. (2003) TI-435 Gene Mutation Assay in Chinese Hamster V79 Cells In Vitro (V79/HPRT). Project Number: 803402. Unpublished study prepared by RCC Umweltchemie GmbH & Co. Kg. 38 p.	46339006	Bayer CropScience	EXC	
870.5375	Schulz, M. (2003) TI-435 In Vitro Chromosome Aberration Test In Chinese Hamster V79 Cells. Project Number: 803403. Unpublished study prepared by RCC Umweltchemie GmbH & Co. Kg. 38 p.	46339007	Bayer CropScience	EXC	



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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.5395	Honarvar, N. (2003) TI-435 Micronucleus Assay in Bone Marrow Cells of the Mouse. Project Number: 803404. Unpublished study prepared by RCC Umweltchemie GmbH & Co. Kg. 27 p.	46339008	Bayer CropScience	EXC	
OECD 486	Honarvar, N. (2003) TI-435 In Vivo/In Vitro Unscheduled DNA Synthesis in Rat Hepatocytes. Project Number: 803405. Unpublished study prepared by RCC Umweltchemie GmbH & Co. Kg. 28 p.	46339009	Bayer CropScience	EXC	
	Fontaine, L. (2004) Product Chemistry of Clothianidin Technical. Project Number: BR/2445, 15/920/2215, ANR/13504. Unpublished study prepared by Bayer Corp. 207 p.	46345601	Bayer CropScience	EXC	
	Arthur, E.; Shepherd, J.; Dominic, A. (2006) [Thiazole-2-(Carbon 14)] Clothianidin: Seed Leaching Study. Project Number: METIX050. Unpublished study prepared by Bayer CropScience LP. 88 p.	46826904	Bayer CropScience	EXC	



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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Cutler, C. (2006) An Investigation of the Potential Long-Term Impact of Clothianidin Seed Treated Canola on Honey Bees, <i>Apis mellifera</i> L. Project Number: 2005/CSD/EBTIX064, EBTIX064, 00554. Unpublished study prepared by Bayer CropScience LP, University of Guelph and Bayer Ag Institut fuer Ruckstands-Analytik. 255 p.	46907801	Bayer CropScience	EXC	
	Cutler, C.; Scott-Dupree, C. (2006) Spring 2006 Assessment of Overwintered Colonies Studied in an Investigation of the Potential Long-Term Impact of Clothianidin Seed Treated Canola on Honey Bees, <i>Apis mellifera</i> L.. Project Number: 2005/CSD/EBTIX064/2, EBTIX064/2. Unpublished study prepared by University of Guelph. 4 p.	46907802	Bayer CropScience	EXC	
	Hammel, K. (2004) Evaluation of the Time-Dependent Sorption of Clothianidin Based on Batch Equilibrium Experiments in Two Soils. Project Number: MEF/04/281, METIX046. Unpublished study prepared by Bayer Ag, Institute of Product Info. & Residue Anal. 31 p.	46913101	Bayer CropScience	EXC	
NONE	Arthur, E.; Shepherd, J.; Dominic, A. (2008) [Thiazolyl-2-(Carbon 14)]-Clothianidin: Seed Leaching Study. Project Number: M/270224/02/1, METIX050/1. Unpublished study prepared by Bayer CropScience. 88 p.	47483002	Bayer CropScience	EXC	



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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Dominic, A.; Arthur, E. (2006) Clothianidin: Long-term Hydrolytic Degradation. Project Number: M/267329/02/1, METIX051/1. Unpublished study prepared by Bayer CropScience. 73 p.	47483003	Bayer CropScience	EXC	
	Memmert, U. (2008) Fate and Ecological Effects of TI-435 50 WG in an Outdoor Freshwater Mesocosm Study. Project Number: M/044250/01/2, DECO/082. Unpublished study prepared by RCC Umweltchemie Ag. 405 p.	47483004	Sumitomo Chemical Company, Ltd	EXC	
	Perez, S.; Perez, R. (2006) Evaluation of TI435-TMG - FDA Multiresidue Method (MRM) Testing. Project Number: M/272961/01/1, RATIY016. Unpublished study prepared by ADPEN Laboratories, Inc. 63 p.	47483008	Bayer CropScience	EXC	
860.1500	Stewart, E. (2008) Clothianidin Residues on Almond from Trials Conducted in the United States in 2007. Project Number: 200800097, SARS/07/71, 060246. Unpublished study prepared by Stewart Agricultural Research Services, Inc. 140 p.	47471601	Sumitomo Chemical Company, Ltd	EXC	



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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
860.1500	Stewart, E. (2008) Clothianidin Residues on Bell and Non-Bell Pepper from Trials Conducted in the United States in 2007. Project Number: 200800096, SARS/07/81, 060252. Unpublished study prepared by Stewart Agricultural Research Services and Golden Pacific Laboratories, LLC (GPL). 126 p.	47471602	Sumitomo Chemical Company, Ltd	EXC	
860.1500	Stewart, E. (2007) Clothianidin Residues on Cabbage from Trials Conducted in the United States in 2006. Project Number: 200800029, SARS/06/83, 060221. Unpublished study prepared by Stewart Agricultural Research Services and Golden Pacific Laboratories, LLC (GPL). 146 p.	47471603	Sumitomo Chemical Company, Ltd	EXC	
860.1500	Stewart, E. (2007) Clothianidin Residues on Cantaloupe from Trials Conducted in the United States in 2006 and 2007. Project Number: SARS/06/78, 200800048, 060218. Unpublished study prepared by Stewart Agricultural Research Services and Golden Pacific Laboratories, LLC (GPL). 119 p.	47471604	Sumitomo Chemical Company, Ltd	EXC	
860.1500	Stewart, E. (2007) Clothianidin Residues on Cauliflower from Trials Conducted in the United States in 2006. Project Number: SARS/06/82, 200800026, 060220. Unpublished study prepared by Golden Pacific Laboratories, LLC (GPL) and Stewart Agricultural Research Services. 153 p.	47471605	Sumitomo Chemical Company, Ltd	EXC	



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860.1500	Stewart, E. (2008) Clothianidin Residues on Celery from Trials Conducted in the United States in 2007. Project Number: SARS/07/76, 200800027, 060250. Unpublished study prepared by Stewart Agricultural Research Services and Golden Pacific Laboratories, LLC (GPL). 147 p.	47471606	Sumitomo Chemical Company, Ltd	EXC	
860.1500 860.1520	Stewart, E. (2008) Clothianidin Residues on Cotton and Cotton Processed Commodities from Trials Conducted in the United States in 2006 and 2007. Project Number: SARS/06/85, 200800095, 060223. Unpublished study prepared by Stewart Agricultural Research Services, and Golden Pacific Laboratories, LLC (GPL) and GLP Technologies. 2262 p.	47471607	Sumitomo Chemical Company, Ltd	EXC	
860.1500	Stewart, E. (2007) Clothianidin Residues on Cucumber from Trials Conducted in the United States in 2006 and 2007. Project Number: SARS/06/77, 200800047, 060217. Unpublished study prepared by Stewart Agricultural Research Services and Golden Pacific Laboratories, LLC (GPL). 143 p.	47471608	Sumitomo Chemical Company, Ltd	EXC	
860.1500	Stewart, E. (2008) Clothianidin Residues on Head Lettuce from Trials Conducted in the United States in 2007. Project Number: SAR/07/74, 060248, VA/032/02. Unpublished study prepared by Stewart Agricultural Research Services and Golden Pacific Laboratories, LLC (GPL). 168 p.	47471609	Sumitomo Chemical Company, Ltd	EXC	



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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
860.1500	Stewart, E. (2008) Clothianidin Residues on Leaf Lettuce from Trials Conducted in the United States in 2007. Project Number: SARS/07/73, 200800099, 060247. Unpublished study prepared by Golden Pacific Laboratories, LLC (GPL) and Stewart Agricultural Research Services. 143 p.	47471610	Sumitomo Chemical Company, Ltd	EXC	
860.1500	Stewart, E. (2007) Clothianidin Residues on Mustard Greens from Trials Conducted in the United States in 2006. Project Number: 200700011, SARS/06/84, 060222. Unpublished study prepared by Stewart Agricultural Research Services and Golden Pacific Laboratories, LLC (GPL). 154 p.	47471611	Sumitomo Chemical Company, Ltd	EXC	
860.1500	Stewart, E. (2007) Clothianidin Residues on Pecan from Trials Conducted in the United States in 2006. Project Number: 200800030, SARS/06/72, 060216. Unpublished study prepared by Golden Pacific Laboratories, LLC (GPL) and Stewart Agricultural Research Services. 120 p.	47471612	Sumitomo Chemical Company, Ltd	EXC	
860.1500 860.1520	Stewart, E. (2008) Clothianidin Residues on Soybean and Soybean Processed Commodities from Trials Conducted in the United States in 2007. Project Number: SARS/07/86, 200800128, 060253. Unpublished study prepared by Golden Pacific Laboratories, LLC (GPL), Stewart Agricultural Research Services and GLP Technologies. 209 p.	47471613	Sumitomo Chemical Company, Ltd	EXC	



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860.1500	Stewart, E. (2008) Clothianidin Residues on Spinach from Trials Conducted in the United States in 2006. Project Number: 060249, SARS/07/75, 200800028. Unpublished study prepared by Stewart Agricultural Research Services and Golden Pacific Laboratories, LLC (GPL). 143 p.	47471614	Sumitomo Chemical Company, Ltd	EXC	
860.1500	Stewart, E. (2007) Clothianidin Residues on Summer Squash from Trials Conducted in the United States in 2006 and 2007. Project Number: SARS/06/79, 060219, 200800049. Unpublished study prepared by Stewart Agricultural Research Services and Golden Pacific Laboratories, LLC (GPL). 120 p.	47471615	Sumitomo Chemical Company, Ltd	EXC	
860.1500 860.1520	Stewart, E. (2008) Clothianidin Residues on Tomato and Tomato Processed Commodities from Trials Conducted in the United States in 2007. Project Number: 200800098, SARS/07/80, 060251. Unpublished study prepared by Stewart Agricultural Research Services, Golden Pacific Laboratories, LLC (GPL) and A.C.D.S. Research, Inc. 209 p.	47471616	Sumitomo Chemical Company, Ltd	EXC	
870.7800	Hobeman, A. (2008) Oral (Diet) Developmental Immunotoxicity Study of TI 435 (Clothianidin) in CrI: CD(SD) Rats. Project Number: 5819/008, RLF00001, 5819/008/TXTIY001. Unpublished study prepared by Charles River Laboratories and ImmunoTox, Inc. 537 p.	47526501	Sumitomo Chemical Company, Ltd	EXC	



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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
860.1500	Stearns, J. (2009) Magnitude of the Residues of Clothianidin on Figs. Project Number: V/08/32571, 200900064. Unpublished study prepared by Valent U.S.A. Corporation and Excel Research Services, Inc. and Research for Hire and California Agricultural Research, Inc. 107 p.	47666901	Sumitomo Chemical Company, Ltd	EXC	
OPPTS 860.1500	Stearns, J. (2009) Magnitude of the Residues of Clothianidin on Pomegranates. Project Number: V/08/32584, 200900059. Unpublished study prepared by Valent U.S.A. Corporation and Excel Research Services, Inc. and Research for Hire and California Agricultural Research, Inc. 110 p.	47666902	Sumitomo Chemical Company, Ltd	EXC	
860.1500 860.1520	Stearns, J. (2001) Magnitude of the Residues of Clothianidin in Apples and Apple Processing Products: Lab Project Number: V12016: TMN-0283. Unpublished study prepared by Valent U.S.A. Corp. 276 p.	45480402	Arysta LifeScience North America, LLC	EXC	
860.1500	Stearns, J. (2001) Magnitude of the Residues of Clothianidin in Pears: Amended Report: Lab Project Number: V12097: TMN-0307. Unpublished study prepared by Valent U.S.A. Corp. 161 p.	45480403	Arysta LifeScience North America, LLC	EXC	



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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
875.2100	Schreier, T. (2001) Dissipation of Dislodgeable Foliar Clothianidin Residues from Pesticide Treated Apple Foliage: Lab Project Number: VP-21400: TMN-0423: V-21400-A. Unpublished study prepared by Valent U.S.A. Corporation. 130 p.	45480404	Arysta LifeScience North America, LLC	EXC	
850.3030 141-2	V-10066: Honeybee (Apis Mellifera L) Toxicity of V-10066 Residues on Foliage [Honey bee]	45490702	Arysta LifeScience North America, LLC	EXC	
164-1	Cassidy, P. (2001) TI-435--Terrestrial Field Dissipation Study, California 1998: Lab Project Number: 98.322: 7572-98-0092: F98908-001. Unpublished study prepared by Plant Sciences, Inc. and Ricerca, LLC. 135 p.	45490703	Arysta LifeScience North America, LLC	EXC	
164-1	Cassidy, P. (2001) TI-435--Terrestrial Field Dissipation Study, Washington 1998: Lab Project Number: QAL 98-54: 7570-98-0093: TMN-0155. Unpublished study prepared by Qualls Agricultural Laboratory and Ricerca, LLC. 130 p.	45490704	Arysta LifeScience North America, LLC	EXC	
164-1	Cassidy, P. (2001) TI-435--Terrestrial Field Dissipation Study, Georgia 1998: Lab Project Number: 7574-98-0091-CR: F98845-001: 98-051. Unpublished study prepared by Research Options, Inc. and Ricerca, LLC. 138 p.	45490705	Arysta LifeScience North America, LLC	EXC	



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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
164-1	Carringer, S. (2002) Terrestrial Field Soil Dissipation of TM-44401 in Established Turf in Illinois: Final Study Report: Lab Project Number: V-99-21194:11027-1: RM-39V. Unpublished study prepared by Ricerca, LLC. 432 p.	45708701	Arysta LifeScience North America, LLC	EXC	
164-1	Carringer, S. (2002) Terrestrial Field Soil Dissipation of TM-44401 in Established Turf in Mississippi: Final Study Report: Lab Project Number: V-99-21186: 11028-1: RM-39V. Unpublished study prepared by Ricerca, LLC. 438 p.	45708702	Arysta LifeScience North America, LLC	EXC	
171-11(2)	Concha, M. (2003) Identification of the Pyrolysis Products of (Ni-14C) TM-444 in Cigarette Smoke. Project Number: 1168W/1, 1168W. Unpublished study prepared by PTRL West, Inc. 89 p.	46027101	Arysta LifeScience North America, LLC	EXC	
860.1340	Reed, D. (2004) Independent Laboratory Validation for the Determination of TM-444 and TMG in Grapes: Final Report. Project Number: ARVESTA/1506. Unpublished study prepared by Pyxant Labs Inc. 53 p.	46346801	Arysta LifeScience North America, LLC	EXC	



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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
860.1500 860.1520	Carringer, S. (2004) Magnitude of the Residue of TM-444 and its Metabolite in Grape Raw Agricultural and Processed Commodities. Project Number: TCI/03/076, ML03/1061/ARV. Unpublished study prepared by Morse Laboratories and National Food Laboratory, Inc. 393 p.	46346802	Arysta LifeScience North America, LLC	EXC	
860.1500	Carringer, S. (2003) Comparison of TM-444 Residues in Potato Raw Agricultural Commodities Following In-Furrow, Side-Dress, and Foliar Applications of TM-444 Formulated Products. Project Number: TCI/02/063, ML02/1016/ARV. Unpublished study prepared by Morse Laboratories and Smith Biological Services and Marbicon, Inc. 201 p.	46357301	Arysta LifeScience North America, LLC	EXC	
860.1500 860.1520	Carringer, S. (2004) Magnitude of the Residue of TM-444 and its Metabolite in Potato Raw Agricultural and Processed Commodities. Project Number: TCI/03/075, ML03/1057/ARV. Unpublished study prepared by Morse Laboratories and National Food Laboratory, Inc. and ACDS Research, Inc. 420 p.	46357302	Arysta LifeScience North America, LLC	EXC	
None	Sabbagh, G.; Dyer, D.; Desmerteau, D. (2006) Mobility Potential of Clothianidin In Soil Profile for Uses on Turf. Project Number: METIY002. Unpublished study prepared by Bayer CropScience LP. 159 p.	46871001	Arysta LifeScience North America, LLC	EXC	



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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
850.1740	Thomas, S.; Krueger, H.; Kendall, T.; et. al. (2007) Clothianidin: A 10-Day Whole Sediment Toxicity Test with Leptocheirus plumulosus Using Spiked Sediment: Final Report. Project Number: 443A/135A, 443/111306/LEP/10D/SUB443. Unpublished study prepared by Wildlife International, Ltd. 80 p.	47199401	Arysta LifeScience North America, LLC	EXC	
	Assaf, N. (2008) Aggregate Human Health Risk Assessment for Clothianidin: Final Study. Project Number: 200800360. Unpublished study prepared by Valent U.S.A. Corporation. 75 p.	47632501	VALENT U.S.A. CORPORATION	EXC	
860.1500	Duah, F. (2002) TI-435 600 FS - Magnitude of the Residue in Sorghum. Project Number: T5046/01H, T5047/01H, T5048/01H. Unpublished study prepared by Bayer Corp. and Gustafson Seed Technology Center. 182 p.	46144901	Bayer CropScience	EXC	
860.1520	Duah, F. (2002) TI-435 600 FS - Magnitude of the Residue in Sorghum Processed Commodities (Request for Waiver of the Study for the Magnitude of the Residue in Sorghum Aspirated Grain Fractions and Processed Commodities). Project Number: T519SO02, 200244, 0104002. Unpublished study prepared by Bayer Corp. and Gustafson Seed Technology Center and Texas A & M Food Protein Research &. 67 p.	46144902	Bayer CropScience	EXC	



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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
860.1500	Krolski, M. (2005) Poncho 600 FS - Magnitude of the Residue in Cotton. Project Number: T519CT01, RCTIY009, 201161. Unpublished study prepared by Bayer Corp., Gustafson Seed Technology Center and Texas A & M Food Protein Research. 159 p.	46482308	Bayer CropScience	EXC	
860.1520	Lenz, C. (2005) Poncho 600 FS - Request for Waiver from the Requirement for a Cotton Processing Study. Project Number: T519CT02, RCTIY010, 201162. Unpublished study prepared by Bayer Corp., Gustafson Seed Technology Center and Texas A & M Food Protein Research. 84 p.	46482309	Bayer CropScience	EXC	
860.1900	Duah, F. (2006) PONCHO 600 FS - Magnitude of the Residue in Field Rotational Crop - Soybeans. Project Number: RATIX046. Unpublished study prepared by Bayer CropScience LP, Bayer Corp. and Bayer Research Farm. 83 p.	46826901	Bayer CropScience	EXC	
860.1500	Duah, F.; Harbin, A. (2006) Clothianidin and Cyfluthrin 600 SE Magnitude of the Residue in/on Sugar Beet. Project Number: RATIY006. Unpublished study prepared by Bayer CropScience LP. 238 p.	47007809	Bayer CropScience	EXC	



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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
860.1520	Duah, F.; Harbin, A. (2006) Clothianidin and Cyfluthrin 600 SE Magnitude of the Residue in/on Sugar Beet Processed Commodities. Project Number: RATIY007. Unpublished study prepared by Bayer Crop Science Lp and GLP Technologies and Pyxant Labs Inc. 310 p.	47007810	Bayer CropScience	EXC	
875.1100	Lunchick, C. (2006) Poncho Beta Sugar Beet Seed Treatment Worker Risk Assessment. Unpublished study prepared by Bayer Crop Science Lp. 7 p.	47007811	Bayer CropScience	EXC	
835.1240	Arthur, E.; Shepherd, J.; Dominic, A. (2008) [Thiazolyl-2-(Carbon 14)]-Clothianidin: Seed Leaching Study. Project Number: M/270224/02/1, METIX050/1. Unpublished study prepared by Bayer CropScience. 88 p.	47483002	Bayer CropScience	EXC	
835.2120	Dominic, A.; Arthur, E. (2006) Clothianidin: Long-term Hydrolytic Degradation. Project Number: M/267329/02/1, METIX051/1. Unpublished study prepared by Bayer CropScience. 73 p.	47483003	Bayer CropScience	EXC	



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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.1300	Qadri, S. (2007) Validation of Bayer CropScience Method TI-002-P05-001: An Analytical Method for the Determination of Clothianidin (TI-435) and the Metabolite TMG Residues in Root and Leafy Vegetables using LC/MS/MS. Project Number: M/289314/01/1, RATIY008. Unpublished study prepared by Bayer CropScience. 105 p.	47483006	Bayer CropScience	EXC	
860.1300	Brookey, F. (2006) Independent Laboratory Validation of the Residue Analytical Method: an Analytical Method for the Determination of Clothianidin (TI-435) and the Metabolite TMG Residues in Root and Leafy Vegetables using LC MS/MS - Method no. TI-002-P05-001: Final Report. Project Number: M/283049/01/1, RATIY018, ML06/1320/BAY. Unpublished study prepared by Morse Laboratories, Inc. 100 p.	47483007	Bayer CropScience	EXC	
860.1300	Perez, S.; Perez, R. (2006) Evaluation of TI435-TMG - FDA Multiresidue Method (MRM) Testing. Project Number: M/272961/01/1, RATIY016. Unpublished study prepared by ADPEN Laboratories, Inc. 63 p.	47483008	Bayer CropScience	EXC	
860.1380	Coopersmith, H. (2008) Storage Stability of TMG in Potatoes (Tuberous Vegetables) and Sugar Beet Leaves (Leaves of Root Vegetables) and Associated Processed Products of Potatoes. Project Number: M/303705/01/1, RATIY015. Unpublished study prepared by Bayer CropScience. 106 p.	47483009	Bayer CropScience	EXC	



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860.1480	Residues in Food or Feed - Residue/Recovery Data by Commodity	47867001	Valent BioScience Corporation	EXC	
860.1500	Clothianidin Residues on Rice and Rice Produced Commodities from Trials Conducted in the United States in 2008	47955203	Valent U.S.A. Corporation	OWN	
860.1500	Duah, F.; Harbin, A. (2006) Poncho 600 FS - Magnitude of the Residue in/on Potato. Project Number: M/282086/01/1, RATIY004. Unpublished study prepared by Bayer CropScience. 147 p.	47483012	Bayer CropScience	EXC	
860.1500	Ballantine, J. (2006) Clothianidin - Magnitude of the Residue in/on Potato. Project Number: M/304969/01/1, AAFCO4/001/R, AAFCO4/001R/568. Unpublished study prepared by University of California, Davis. 223 p.	47483013	Bayer CropScience	EXC	
860.1500	Freeseaman, P.; Harbin, A. (2008) Poncho-Beta 453.3 FS - Magnitude of the Residue in/on Carrots and Radishes. Project Number: M/304701/01/1, RATIP043. Unpublished study prepared by Bayer CropScience. 238 p.	47483014	Bayer CropScience	EXC	



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860.1500	Freeseaman, P.; Harbin, A. (2008) Magnitude of the Clothianidin Residue in/on Wheat Following Seed Treatment with Poncho 600 FS and Prothioconazole 480 SC. Project Number: M/304371/01/1, RATIP044. Unpublished study prepared by Bayer CropScience. 189 p.	47483015	Bayer CropScience	EXC	
860.1500	Gould, T.; Dallstream, K. (2008) Clothianidin+Imidacloprid WS (56.25 percent+18.75 percent w/w) - Magnitude of the Residue in/on Leafy Greens (Crop Subgroup 4A). Project Number: M/304730/01/1, RATIL001. Unpublished study prepared by Bayer CropScience. 221 p.	47483017	Bayer CropScience	EXC	
860.1500	Gould, T.; Dallstream, K. (2008) Clothianidin+Imidacloprid WS (56.25 percent+18.75 percent w/w) - Magnitude of the Residue in/on Brassica Leafy Vegetables. Project Number: M/304704/01/1, RATIL002. Unpublished study prepared by Bayer CropScience. 219 p.	47483018	Bayer CropScience	EXC	
860.1500	Freeseaman, P.; Harbin, A. (2008) Magnitude of the Clothianidin Residue in/on Wheat Following Seed Treatment with Poncho 600 FS and Prothioconazole 480 SC. Project Number: M/304551/01/1, RATIP046. Unpublished study prepared by Bayer CropScience. 272 p.	47483019	Bayer CropScience	EXC	



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860.1500	Freeseaman, P.; Harbin, A. (2008) Poncho-Beta 453.3 FS - Magnitude of the Residue in/on Cucurbit Vegetables (Crop Group 9). Project Number: M/300700/01/1, RATIP045. Unpublished study prepared by Bayer CropScience. 198 p.	47483020	Bayer CropScience	EXC	
860.1500	Freeseaman, P.; Harbin, A. (2008) Magnitude of the Clothianidin Residue in/on Wheat Following Seed Treatment with Poncho 600 FS and Prothioconazole 480 SC. Project Number: M/303764/01/1, RATIY013. Unpublished study prepared by Bayer CropScience. 282 p.	47483021	Bayer CropScience	EXC	
860.1520	Duah, F.; Helfrich, K. (2006) Poncho 600 FS - Magnitude of the Residue in/on Potato Processed Commodities. Project Number: M/282378/01/1, RATIY005. Unpublished study prepared by Bayer CropScience and National Food Laboratory, Inc. 169 p.	47483022	Bayer CropScience	EXC	
860.1520	Lenz, C. (2008) Poncho-Beta 453.3 FS - Magnitude of the Residue in/on Tomato Processed Commodities. Project Number: M/304478/01/1, RATIP041. Unpublished study prepared by Bayer CropScience and GLP Technologies. 87 p.	47483023	Bayer CropScience	EXC	



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Applicant's/Registrant's Name & Address VALENT U.S.A. CORPORATION  
1600 Riviera Avenue, Suite 200 Walnut Creek, CA 94596

Product: CLOTHIANIDIN TECHNICAL

Ingredient: CLOTHIANIDIN

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
860.1520	Lenz, C. (2008) Poncho 600 FS - Request for Waiver of the Study of the Magnitude of the Residue in/on Wheat Processed Commodities. Project Number: M/304174/01/1, RATIP037. Unpublished study prepared by Bayer CropScience and GLP Technologies. 76 p.	47483024	Bayer CropScience	EXC	
875.1100	Maasfeld, W. (2008) Determination of Exposure to Pencycuron During Loading and Application of MoncereenR-Droogontsmetter (Monceren DS 12.5) in Potato Fields. Project Number: M/043846/01/2, MR/565/01, P/666/01/1502. Unpublished study prepared by Bayer AG. 49 p.	47483031	Bayer CropScience	EXC	
875.1100	Lunchick, C. (2008) Assessment of Worker Exposure and Risk Resulting from Commercial Treatment of Vegetable Seeds and Commercial and On-Farm Treatment of Cereals and Potato Seed-Pieces with Sepresto 75WS. Project Number: M/305114/01/1, G201919. Unpublished study prepared by Bayer CropScience LP. 24 p.	47483032	Bayer CropScience	EXC	
SUPP	Tang, Z. (2008) Groundwater Exposure Assessment for Clothianidin from Proposed Uses on Vegetables and Cereal Grains. Project Number: M/304828/01/1, RATIY024. Unpublished study prepared by Bayer CropScience. 61 p.	47483033	Bayer CropScience	EXC	



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SUPP	Lantz, J.; Tang, Z.; Desmarteau, D. (2008) Acute and Chronic Dietary Exposure Assessments for Clothianidin: Sepresto Submission. Project Number: M/305112/01/1, G201914. Unpublished study prepared by Bayer CropScience LP. 38 p.	47483034	Bayer CropScience	EXC	
SUPP	Lunchick, C. (2008) Assessment of Worker Exposure and Risk Resulting from Commercial Treatment of Vegetable Seeds with Sepresto 75 WS. Project Number: M/305586/01/1, G201925. Unpublished study prepared by Bayer CropScience. 12 p.	47483035	Bayer CropScience	EXC	
875.1100	Lunchick, C. (2008) Assessment of Worker Exposure and Risk Resulting from On-Farm and Commercial Treatment of Wheat, Barley, and Triticale with Proceed Optimum. Project Number: G201924. Unpublished study prepared by Bayer CropScience. 13 p.	47483309	Bayer CropScience	EXC	
860.1900	Duah, F. K.; Dallstream, K. A.; Lemke, V. J. (2008) Poncho 600 FS - Magnitude of the Residue in Soybeans (Rotational Crop Tolerance 30-Day PBI). Project Number: M/304695/01/1, RATIY011, TI003/05R. Unpublished study prepared by Bayer CropScience. 227 p.	47524001	Bayer CropScience	EXC	
None	Physical/Chemical Characteristics	47955201	Valent U.S.A. Corporation	OWN	



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None	Exposure or Risk to Non-Target Organisms	47972301	Bayer CropScience	EXC	
None	Exposure or Risk to Non-Target Organisms	47972302	Bayer CropScience	EXC	
None	Exposure or Risk to Non-Target Organisms	47972303	Bayer CropScience	EXC	
None	Exposure or Risk to Non-Target Organisms	47972304	Bayer CropScience	EXC	
None	Pesticide Fate in the Environment (General)	47972307	Bayer CropScience	EXC	
None	Pesticide Effects on Non-target Animals (Including Man)	47975300	Bayer CropScience	EXC	
None	Fate of Pesticides in Plants (Metabolism)	47975301	Bayer CropScience	EXC	

Signature

*hisa V. Carter*

*for*

Name and Title: SUE-CHI SHEN

Date

REGULATORY PROJECT MANAGER

JUNE 09, 2011

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Date:  
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Product:  
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Active Ingredient:  
**CLOTHIANIDIN**

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EPA Reg No./ File Symbol: **59639-173**

Total Pages = **1**

Applicant's/Registrant's Name & Address **VALENT U.S.A. CORPORATION**  
**1600 Riviera Avenue, Suite 200 Walnut Creek, CA 94596**

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			Sumitomo Chemical Company, Ltd	EXC	
			Sumitomo Chemical Company, Ltd	EXC	
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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Bayer CropScience	EXC	
			Bayer CropScience	EXC	
			Bayer CropScience	EXC	
			Bayer CropScience	EXC	



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Product:  
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Active Ingredient:  
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EPA Reg No./ File Symbol: 59639-173

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Applicant's/Registrant's Name & Address VALENT U.S.A. CORPORATION  
1600 Riviera Avenue, Suite 200 Walnut Creek, CA 94596

Product: CLOTHIANIDIN TECHNICAL

Ingredient: CLOTHIANIDIN

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Bayer CropScience	EXC	
			Bayer CropScience	EXC	
			Bayer CropScience	EXC	
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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Bayer CropScience	EXC	
			Sumitomo Chemical Company, Ltd	EXC	
			Bayer CropScience	EXC	
			Sumitomo Chemical Company, Ltd	EXC	



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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Sumitomo Chemical Company, Ltd	EXC	
			Sumitomo Chemical Company, Ltd	EXC	
			Sumitomo Chemical Company, Ltd	EXC	
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			Sumitomo Chemical Company, Ltd	EXC	
			Sumitomo Chemical Company, Ltd	EXC	
			Arysta LifeScience North America, LLC	EXC	
			Arysta LifeScience North America, LLC	EXC	



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			Arysta LifeScience North America, LLC	EXC	
			Arysta LifeScience North America, LLC	EXC	
			Arysta LifeScience North America, LLC	EXC	
			Arysta LifeScience North America, LLC	EXC	
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			VALENT U.S.A. CORPORATION	EXC	
			Bayer CropScience	EXC	
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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Valent BioScience Corporation	EXC	
			Valent U.S.A. Corporation	OWN	
			Bayer CropScience	EXC	
			Bayer CropScience	EXC	
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Product: CLOTHIANIDIN TECHNICAL

Ingredient: CLOTHIANIDIN

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Bayer CropScience	EXC	
			Bayer CropScience	EXC	
			Bayer CropScience	EXC	
			Bayer CropScience	EXC	



Date:  
09 JUNE 2011

Product:  
CLOTHIANIDIN TECHNICAL

Active Ingredient:  
CLOTHIANIDIN

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
1200 Pennsylvania Avenue  
WASHINGTON, D.C. 20460-0001

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DATA MATRIX

Date: JUNE 09, 2011

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			Bayer CropScience	EXC	
			Bayer CropScience	EXC	
			Bayer CropScience	EXC	
Signature	Lia V. Cortes		Name and Title: SUE-CHI SHEN		Date
	for		REGULATORY PROJECT MANAGER		JUNE 09, 2011

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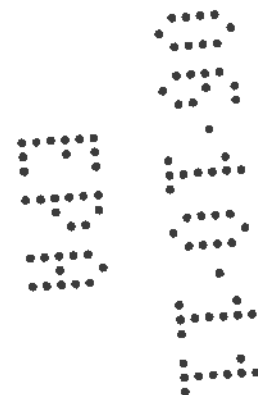
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Sally S. Christopher  
Labeling Specialist  
Registration and Regulatory Affairs  
Valent U.S.A. Corporation

June 9, 2011  
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